## Exhibit H

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Page 1
 1
                  IN THE DISTRICT COURT
 2
               438TH JUDICIAL DISTRICT
 3
                   BEXAR COUNTY, TEXAS
 4
 5
     JENNIFER RAMIREZ F/K/A
     JENNIFER GALINDO
 6
              Plaintiff,
                                ) Cause No.
 7
                                ) 2012-CI-18690
         VS.
 8
     CESAR REYES, JOHNSON &
 9
     JOHNSON, INC., AND
     ETHICON, INC.
10
              Defendants.
11
12
13
14
               THURSDAY, MARCH 24, 2016
15
16
            Deposition of PEGGY PENCE, PH.D., held
17
     at Lopez McHugh, LLP, 100 Bayview Circle,
     Suite 5600, Newport Beach California,
18
19
     commencing at 9:36 a.m., on the above date,
     before Lisa Moskowitz, California Certified
20
21
     Shorthand Reporter No. 10816, RPR, CLR.
22
23
               GOLKOW TECHNOLOGIES, INC.
           877.370.3377 ph | 917.591.5672 fax
24
                     Deps@golkow.com
25
```

Page 2  APPEARANCES:  FREESE & GOSS, PLLC BY: TIM K. GOSS, ESQ.  tim@freeseandgoss.com YVETTE DIAZ, ESQ.  yvette@freeseandgoss.com 3031 Allen Street, Suite 200  Dallas, Texas 75204 (214) 761-6610  Counsel for Plaintiff	1 DEPOSITION EXHIBITS 2 NUMBER DESCRIPTION PAGE 3 11 FDA Public Health Notification 206 4 12 AdvaMed's 40th Anniversary 280 5 13 Guidance for Industry and FDA 286 Staff 6 14 Curriculum Vitae 315 7 15 Deposition and Trial Testimony 350 8 Reviewed 9 16 Safety Principle PowerPoint 354 10 17 Johnson & Johnson Credo 357	Page 4
9 BUTLER SNOW, LLP BY: KARI L. SUTHERLAND, ESQ. 10 kari.sutherland@butlersnow.com 1200 Jefferson Avenue, Suite 205 11 Oxford, Mississippi 38655 (662) 513-8000 12 Counsel for Defendants Johnson & 13 Johnson and Ethicon, Inc. 14 SCOTT, CLAWATER & HOUSTON, LLP 15 BY: CAROL Y. VERBEEK, ESQ. (By Telephone) cverbeek@schlawyers.com 16 2727 Allen Parkway, Suite 500 Houston, Texas 77019 17 (713) 650-6600 18 Counsel for Defendant Cesar Reyes, M.D. 19 20 21	11 18 Exhibit 2 to Supplemental 364 Report  12 19 Baptist Health System Surgery 367  13 Implant/Prosthesis Record  14 20 Due Diligence Growth 370 Opportunity Outline  15 21 Email Chain, dated 4/14/03 378  16 22 Email from Ronnie Toddywala, 385 dated 6/24/03  18 23 Gynecare Sales Training Launch 389 Meeting  19 24 GHTF Final Document, dated 395 5/20/05  21 25 GHTF Final Document, dated 401 May, 2007	
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6 7 8 DEPOSITION EXHIBITS 9 NUMBER DESCRIPTION PAGE 10 1 Second Amended Notice 9 11 2 FDA Device Labeling Guidance 15 G91-1 12 3 Expert Report of Peggy Pence, 19 13 Ph.D., RAC, FRAPS 14 4 Peggy Pence, Ph.D., RAC, 20 FRAPS, Expert Witness Report, 15 First Supplemental 16 5 Second Supplemental Reliance 20 List 17 6 Supplemental Report of Peggy 22 18 Pence, Ph.D., RAC, FRAPS 19 7 Exhibit 1 to Supplemental 23 Report	Eberhard's Letter of 18.10.04  1	
Report  8 Deposition and Trial Testimony 45  21 of Peggy Pence, Ph.D., RAC, FRAPS  22  9 Global Harmonization Task 144  23 Force Final Document  24 10 Gynecare TVT Obturator System 146  IFU	Proceedings  18  41 Memo from Allison London Brown 466  19  42 Email from Shalot Armstrong, 475  20 dated 9/1/10  21 43 Email Chain, dated 7/5/10 477  22 44 Email Chain, dated 10/5/10 482  23 45 Email Chain, dated 8/24/10 485  24 46 ADM Module 2: Compliance 488	

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		Page 6			Page 8
1	QUESTIONS NOT ANSWERED	. age c	1	the line? Hello? Do you have it muted?	· ugo o
2	PAGE LINE		2	THE VIDEOGRAPHER: Counsel will	
3	58 12		3		
]	59 20			be noted on the stenographic record.	
1	39 20		4	The court reporter is Lisa Moskowitz,	
4			5	and she will now swear in the witness.	
5			6		
6			7	PEGGY PENCE, PH.D.,	
7			8	after having been duly sworn, was examined	
8			9	and testified as follows:	
9			10		
10			11	MS. VERBEEK: This is Carol	
11			12	Verbeek. I'm sorry, I lost you.	
12			13	· · · · · · · · · · · · · · · · · · ·	
13				MS. SUTHERLAND: Okay. We're	
14			14	back.	
15			15	MS. VERBEEK: Okay.	
16			16		
17			17	EXAMINATION	
18			18	BY MS. SUTHERLAND:	
19			19	Q. Good morning, Dr. Pence.	
20			20	A. Good morning.	
21			21	Q. Would you please tell me your full	
22			22	name?	
23			23	A. Peggy Jo Clark Pence.	
23			24		
				Q. And your address?	
25			25	A. 1533 Miramar Drive, Newport Beach,	
		D 7			D= == 0
1	NEWDORT REACH, CALIFORNIA	Page 7	1	California 02661	Page 9
1	NEWPORT BEACH, CALIFORNIA	Page 7	1	California 92661.	Page 9
2	NEWPORT BEACH, CALIFORNIA THURSDAY, MARCH 24, 2016, 9:36 A.M.	Page 7	2	Q. And Dr. Pence, do you still have a	Page 9
2	THURSDAY, MARCH 24, 2016, 9:36 A.M.	Page 7	2 3	Q. And Dr. Pence, do you still have a company that you work under?	Page 9
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	. Pa	age 10		Page :	12
1	document similar to this before.		1	Q. Yeah. And I really could not	
2	A. Yes, I have.		2	remember myself. I was not trying to put	
3	Q. All right. Did you bring some		3	you on the spot.	
4	stuff with you today with respect to your		4	Do you want this back?	
5	opinions in this case?		5	A. Yeah, just because I can	
	A. Yes.				
6			6	double-check to make sure I'm giving you the	
7	Q. And what all have you brought with		7	right name for the acronym.	
8	you?		8	Q. Thank you.	
9	A. I brought my report from April,		9	A. I believe it is the International	
10	2015, and a copy of my supplemental report,		10	Medical Device Regulators Forum, but I'll	
11	dated I think it was March 2, 2016, and		11	check. Yes. International Medical Device	
12	some copies of Global Harmonization Task		12	Regulators Forum.	
13	Force guidances, and my deposition and trial		13	Q. Okay. And when did they, I guess,	
14	testimony history.		14	come into existence and the GHTF went out of	
15	Q. Oh. Let me see the GHTF's		15	existence?	
16	guidances that you brought.		16	A. It was in the 2011 to 2012 time	
17	A. My supplemental report is in there		17	frame.	
18	as well.		18	Q. All right. Was it before the two	
19	Q. Okay. I may not mark these because		19	guidances that you brought with you were	
20	I think I got them previously.		20	promulgated?	
21	A. And the one you have previously is		21	A. These well, there are other	
22	actually more comprehensive. It has some of		22	guidances in here as well. These were GHTF	
23	the older ones as well.		23	guidances. They are on the IMDRF website as	
24	Q. In your great binder?		24	current documents with the notation from	
25	A. Yes. That I haven't gotten back		25	IMDRF that they are to be considered current	
	711 1001 That I have the gotten back			In Draw charterly and to be complained carrent	
	D	age 11		Page :	13
1	yet.	age 11	1	documents and as time progresses, IMDRF will	١٦
2	Q. Golkow has?		2	reissue them as IMDRF documents. But for	
3	A. Yes.		3	the present time, they're GHTF documents.	
4	Q. All right. So what I'm looking at		4	Q. Okay. And those guidance	
5	you have a GHTF guidance document entitled		5	documents, the two that I called out, are	
6	"Essential Principles of Safety and		6	dated November, 2012?	
7	Performance of Medical Devices," dated		7	A. They	
8	November 2, 2012. And a GHTF final guidance		8	Q. And I know they're preceded by	
9	entitled "Principles of Conformity		9	others.	
10	Assessment For Medical Devices," dated		10	A. Yes, and they are GHTF documents,	
11	November 2, 2012. Correct?		11	though. They are not IMDRF. They were	
12	A. Correct.		12	documents that were produced through the	
13	Q. While I'm looking at these dates,		13	GHTF process.	
14	I've got a question for you. Am I correct		14	Q. Were they finalized before the	
15	that the GHTF changed to a different		15	GHTF, I guess, for lack of a better term,	
16	organization in 2011?		16	went out of business?	
17	A. I believe it was 2011 or 2012, yes.		17	A. I presume so since they were signed	
18	The GHTF disbanded, and its work was		18	off by GHTRF. So they must have been a part	- 1
19	transferred to IMDRF.		19	of finalizing their final work. The	
20	Q. And tell me again what the IMDRF		20	transition was supposed to have been in	
21	stands for.		21	2012. In that 2011/2012 time frame. 2012	
22	A. I know that. Medical Device		22	is what I have in my report.	
23	Regulators International Medical Devices		23	Q. Okay. I think you said GHTRF.	ı
24	Regulators Forum. I believe, and I can just		24	A. I'm sorry. GHTF. Sorry.	
				,	
25	double-check that.		25	Q. No worries. No worries. I just	

	Page 14			Page 16
1	want to make sure we're straight.	1	A. And one in 2015. And I asked my	
2	A. It stands for Global Harmonization	2	staff to pull out any additional references	
3	Task Force.	3	that I hadn't already pulled out in my 2014	
4	Q. Got it.	4	report, and I believe that's what these are.	
5	What else have you brought with you	5	Q. Okay. So if I'm following	
6	today?	6	correctly, what you've got sort of marked	
			here beginning with reference 217 and	
7	A. I think I have one guidance	7		
8	document, MDA guidance document, the device	8	skipping some but going up through	
9	label guidance number G91-1 Blue Book Memo.	9	actually 545B are references that are in	
10	Q. Okay. Do you mind if I take a peak	10	your 2015 TVT-O supplemental report that	
11	at that?	11	were not in your 2014 TVT-O report?	
12	A. Oh, sure.	12	A. Yes. That's my understanding.	
13	Q. Okay. And that's obviously	13	That's what I asked my staff to do. I've	
14	referenced throughout your report on your	14	not verified it personally, but that's what	
15	labeling opinions?	15	I understand that to be.	
16	A. Yes.	16	Q. And are the references that you've	
17	Q. This is a different format for	17	got marked here up at the top the footnote	
18	printing than I have seen.	18	numbers?	
19	A. I probably didn't do the PDF	19	A. Yes.	
20	version.	20	Q. All right. I'm just going to call	
21	Q. Did you just print this out	21	those out for the record so that I'll know	
22	yesterday?	22	what they are and that way I don't think we	
23	A. Yes, last night.	23	need to mark another binder of yours.	
24	Q. All right. I'm just going to mark	24	A. Sounds good.	
25	it. I think it's the same thing, but I'm	25	Q. The first one is reference 217.	
	Tall I allin to the same alling, sat I m		Q. The first one is reference 2171	
	Page 15			Page 17
1	Page 15 iust going to mark it as Exhibit Number 2.	1	The next one is 218, 219, 224A, 224B,	Page 17
1 2	just going to mark it as Exhibit Number 2.	_	The next one is 218. 219. 224A. 224B. 230. 231A. 231B. 232. 259. 313A. And	Page 17
2	just going to mark it as Exhibit Number 2. (Exhibit Number 2 was	2	230. 231A. 231B. 232. 259. 313A. And	Page 17
2	just going to mark it as Exhibit Number 2. (Exhibit Number 2 was marked for identification.)	2	230. 231A. 231B. 232. 259. 313A. And 545B.	Page 17
2 3 4	just going to mark it as Exhibit Number 2.  (Exhibit Number 2 was  marked for identification.) BY MS. CAREY:	2 3 4	230. 231A. 231B. 232. 259. 313A. And 545B.  And actually, what I may do to save	Page 17
2 3 4 5	just going to mark it as Exhibit Number 2.  (Exhibit Number 2 was marked for identification.) BY MS. CAREY: Q. I'll hand that back to you.	2 3 4 5	230. 231A. 231B. 232. 259. 313A. And 545B.  And actually, what I may do to save me even more work is I might get a copy of	Page 17
2 3 4 5 6	just going to mark it as Exhibit Number 2.  (Exhibit Number 2 was marked for identification.) BY MS. CAREY: Q. I'll hand that back to you. A. Thank you.	2 3 4 5 6	230. 231A. 231B. 232. 259. 313A. And 545B.  And actually, what I may do to save me even more work is I might get a copy of this at a break just of your references.	Page 17
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					1
	and the different Early attended to the	Page 18	4	in this case on TOT Other T	Page 20
1	entitled "Clinical Evaluation," dated		1	in this case on TVT-O that I've marked as	
2	May 2007.		2	number 4.	
3	A. Yes. And then behind each of the		3	(Exhibit Number 4 was	
4	tabs in that binder after the supplemental		4	marked for identification.)	
5	report are other GHTF guidances.		5	BY MS. SUTHERLAND:	
6	Q. Oh, okay. I see. I was getting my		6	Q. And it has on the front that same	
7	reports mixed up. This is your what I		7	Exhibit 3 down at the bottom.	
8	call your MDL supplemental report, but it's		8	A. Right. So that Exhibit 3 is	
9	your March, 2016, supplemental report?		9	overwritten by this sticker Exhibit 4; is	
10	A. That's correct. That's correct.		10	that correct?	
11	Q. With some guidances from GHTF		11	Q. Yeah. For this deposition, that	
12	behind it. Which, in fairness, I think, I		12	supplemental TVT-O report is Exhibit 4.	
13	already have from your previous deposition.		13	A. Okay.	
14	A. Yes.		14	Q. The yellow sticker.	
15	Q. So I will hand that back to you.		15	A. Without going through it page by	
16	A. Thank you.		16	page, it appears to be the complete report.	
17	Q. And then just because I know Madam		17	Q. Okay. And now I'm going to hand	
18	Court Reporter has been waiting on it, I'm		18	you what I've marked as Exhibit 5, which I	
19	going to mark what I have as your 2014		19	understand to be your second supplemental	
20	report.		20	reliance list. Take a look at that.	
21	A. Okay.		21	(Exhibit Number 5 was	
22	Q. And let you just identify that for		22	marked for identification.)	
23	me and make sure we're on the same page.		23	BY MS. SUTHERLAND:	
24	I've marked that as Exhibit 3.		24	Q. And does that appear to be your	
25	///		25	reliance list for your TVT-O opinions in the	
		Page 19			Page 21
1	(Exhibit Number 3 was	Page 19	1	Ramirez case, other than what you've got,	Page 21
1 2	(Exhibit Number 3 was marked for identification.)	Page 19	1 2	Ramirez case, other than what you've got, like, footnoted in your report?	Page 21
2	marked for identification.)	Page 19		Ramirez case, other than what you've got, like, footnoted in your report?  A. It's cumulative. I have other	Page 21
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	Page 22			Page 24
1	what I've marked as Exhibit 6.	1	A. It also has the pelvic organ	
2	(Exhibit Number 6 was	2	prolapse products. I do believe I brought a	
3	marked for identification.)	3	copy of that. I have it here.	
4	THE WITNESS: I do reserve the	4	Q. Okay. So looking at what we've	
5		5	- · ·	
	right to add to this.		marked as far as your reports and exhibits	
6	BY MS. CAREY:	6	to reports, do those encapsulate, first of	
7	Q. I'm going to ask you about that.	7	all, your opinions in this case?	
8	Now, is Exhibit Number 6 your TVT-O	8	A. Yes.	
9	supplemental report dated March 2, 2016?	9	Q. All right. Do those items that	
10	A. It is the body of the report, but	10	I've marked, not the deposition notice but	
11	it is missing the exhibits.	11	otherwise up to Deposition Exhibit Number 7,	
12	Q. Actually, in fairness, it's TVT and	12	would those all encapsulate the bases or the	
13	TVT-O supplemental report from March, 2016?	13	documents that you've relied on for your	
14	A. That's correct.	14	opinions in this case?	
15	Q. All right. And you said that had	15	A. Yes.	
16	an exhibit to it?	16	Q. Okay. You mentioned something	
17	A. Two exhibits.	17	about reserving the right to supplement your	
18	Q. And I confess I evidently didn't	18	numerous reports. As you sit here today, do	
19	bring the second exhibit, but I've marked as	19	you have an intention to supplement any of	
20	Exhibit Number 7 what had been marked as	20	your reports related to TVT-O?	
21	Exhibit 1 to the TVT and TVT-O supplemental	21	A. At the present time, I'm not	
22	report, which is applicable industry	22	anticipating a supplement. If new	
23	standards; correct?	23	information becomes available or after	
24	A. That's correct.	24	reviewing reports of other experts, it's	
25		25	appropriate for me to supplement my reports,	
23		23	appropriate for the to supplement my reports,	
	Page 23			Page 25
1	Page 23 (Exhibit Number 7 was	1	then I reserve the right to do that.	Page 25
1 2	(Exhibit Number 7 was	1 2	then I reserve the right to do that.  O. Certainly, But in fairness, as you	Page 25
2	(Exhibit Number 7 was marked for identification.)	2	Q. Certainly. But in fairness, as you	Page 25
2	(Exhibit Number 7 was marked for identification.) BY MS. CAREY:	2	Q. Certainly. But in fairness, as you sit here today, you don't have any ideas in	Page 25
2 3 4	(Exhibit Number 7 was marked for identification.) BY MS. CAREY: Q. All right. And I don't know if you	2 3 4	Q. Certainly. But in fairness, as you sit here today, you don't have any ideas in your head of things you already want to	Page 25
2 3 4 5	(Exhibit Number 7 was marked for identification.) BY MS. CAREY: Q. All right. And I don't know if you remember, but what was Exhibit 2?	2 3 4 5	Q. Certainly. But in fairness, as you sit here today, you don't have any ideas in your head of things you already want to supplement?	Page 25
2 3 4 5 6	(Exhibit Number 7 was marked for identification.) BY MS. CAREY: Q. All right. And I don't know if you remember, but what was Exhibit 2? A. Exhibit 2 is a tabular presentation	2 3 4 5 6	Q. Certainly. But in fairness, as you sit here today, you don't have any ideas in your head of things you already want to supplement?  A. Not at this point in time.	Page 25
2 3 4 5 6 7	(Exhibit Number 7 was marked for identification.) BY MS. CAREY: Q. All right. And I don't know if you remember, but what was Exhibit 2? A. Exhibit 2 is a tabular presentation of the numbers of MDR reports through 2015	2 3 4 5 6 7	Q. Certainly. But in fairness, as you sit here today, you don't have any ideas in your head of things you already want to supplement?  A. Not at this point in time. Q. Okay. And obviously, if you did	Page 25
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			icc,		
		Page 26			Page 28
1	there's anything new that's presented, I		1	A. Not as I sit here today.	
2	would review that.		2	Q. And when you say that you had	
3	Q. Have you asked for anything to		3	reviewed medical records, would those have	
4	review in this case that you haven't already		4	been the exhibits to the doctor's	
5	been given?		5	deposition?	
6	A. To the best of my recollection, as		6	A. That's correct.	
7	I sit here today, no.		7	Q. All right. Does your reliance list	
8	Q. Did you review well, first of		8	that I marked as Exhibit Number 5 include	
9	all, the plaintiff in this case is Jennifer		9	all of the medical literature that you've	
10	Ramirez; right?		10	reviewed, or is there a separate listing of	
11	A. Yes.		11	the literature?	
12	Q. Have you reviewed her medical		12	A. There is literature in here.	
13	records?		13	There's also literature in my prior reports	
14	A. I've reviewed not all of her		14	that's in my reliance list.	
				·	
15	medical records in their entirety but an		15	Q. As an attachment to your report?	
16	overview of her medical records through		16	A. Exhibit B in my reports includes	
17	depositions that I've reviewed of her care.		17	reliance list. So there's medical and	
18	Q. Okay. Let me make sure I well,		18	scientific literature included there.	
19	do you have a listing of items specific to		19	Q. Okay.	
20	this case that you've reviewed? You know		20	A. And literature is also footnoted	
21	what I'm talking about? The plaintiff		21	as referenced as footnotes throughout the	
22	deposition? In-plainor deposition?		22	body of the report as well, and then there's	
23	<ul> <li>A. I would have to look at the</li> </ul>		23	literature that is included in the March 17,	
24	reliance list to see if those are included.		24	2016, reliance list as well.	
25	Q. Do you mind? Let's just take a		25	Q. All right. Is there literature	- 1
-					-
		Page 27			Page 29
					,
1	minute. I just want to be sure I know for		1	that you've reviewed that would be listed	
2	this particular case what you've looked at.		2	elsewhere other than those places you just	
2	this particular case what you've looked at.  A. Okay.		2	elsewhere other than those places you just told me about?	
2 3 4	this particular case what you've looked at. A. Okay. Q. And I think I've got it on the very		2 3 4	elsewhere other than those places you just told me about?  A. The Appendix C to my report	
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Page 30 Page 32 reliance lists and your appendices? 1 THE WITNESS: Do you want me to 1 2 MR. GOSS: Be careful. This is 2 restate it? 3 where Hilary Clinton got in trouble. 3 MR. GOSS: Yes. 4 MS. SUTHERLAND: Do you have an 4 MS. SUTHERLAND: Yeah. 5 5 email server for all the secret email of BY MS. SUTHERLAND: 6 plaintiff counsel -- strike that. 6 Q. Is there a piece of medical 7 Read back my original question. 7 literature, peer-reviewed publication, 8 (Record read by the reporter as follows: 8 that's come out in the past six months specific to TVT-O that is of significance to 9 The reason I'm asking is there a file you keep at 9 10 home specific to pelvic mesh that might include 10 you in your opinions in this case? 11 additional items other than what we've got on all 11 MR. GOSS: Objection. Form. your reliance lists and appendices?") THE WITNESS: You're talking 12 12 THE WITNESS: There are a large 13 13 about solely scientific literature? number of publications that are cited in BY MS. SUTHERLAND: 14 14 the various documents that we've just 15 15 Q. Yes, ma'am. been -- or that are included in the A. There continues to be. I can't 16 16 various documents that we have just been speak to the six months specifically without 17 17 18 discussing. There may be other 18 looking back at literature and confirming documents that I have reviewed more 19 it's within the last six months. There 19 20 recently that -- looking at certain 20 continues to be literature published that 21 update -- you know, updated reports 21 substantiates my opinions. coming out routinely that may not have 22 22 Q. Okay. Give me an example -- the made it into the reliance list at this reason I'm asking is just to see if there's 23 23 24 point in time because I do my best to 24 something that has come out recently that 25 might not be on your reliance list that stay current, but I'm becoming aware of 25 Page 31 Page 33 new literature all the time. 1 you're thinking of today. 1 2 2 So it may be that there are A. For example, I believe it's 3 publications that have not yet made it 3 Dr. Ross and the publication that's five-year results of a study that she had 4 into a reliance list that I do have in 4 5 my files at home. I try to be as 5 done with obturator versus -- if I recall 6 comprehensive as possible, but as you 6 correctly, it wasn't the Ethicon product but 7 7 another obturator -- transobturator sling can see --8 8 BY MS. SUTHERLAND: versus the retropubic sling approach. Her 9 O. It's extensive. 9 publication. 10 A. -- it's extensive. 10 That, I've just recently reviewed Q. If there was new stuff, are you in the last couple of weeks. Things of that 11 11 talking about things that might have come nature. But nothing that has changed my 12 12 out within the past six months or so that opinions but provides further support for my 13 13 might just not have made it to the list yet? 14 14 opinions. 15 A. Yes. Or even within the last year 15 Q. And do you do, like, a weekly that I just may not have had an opportunity PubMed search to find new literature? 16 16 to review yet or am in the process of A. No. I don't do it weekly. 17 17 18 reviewing. 18 Q. How often do you do a literature Q. With respect to TVT-O, is there any search to make sure you're getting the most 19 19 20 piece of literature that's come out 20 up-to-date literature that might address within -- I'm going to limit it to six 21 21 pelvic mesh? months -- that was of significance to you 22 22 A. Periodically. I don't have a set and your opinions in this case? schedule but periodically. 23 23 Q. When's the last time, for instance, 24 MR. GOSS: I'm sorry. Can you 24 25 25 that you did a PubMed search? say that --

Page 34 Page 36 Class 2 device. They were reviewed, I 1 A. Probably within the last two 1 should say, in the same framework as a 2 2 months. 3 3 Q. And do you do something besides Class 2 device. 4 4 PubMed? BY MS. SUTHERLAND: 5 5 A. I do ask counsel if there's any new Q. Okay. Let me make sure I'm on the literature that they're aware of as well 6 6 same page with you for that. 7 that would be important for me to review. 7 For the instruments that are within 8 8 So that's -- I do look for, for example, the TVT-O kit --9 Cochran reviews, things of that nature. 9 A. That's correct. 10 Q. Now, I had limited my question to 10 Q. -- for insertion, were those 11 literature, and you had specifically asked 11 instruments already reviewed as Class 2 because they were part of the 510(k) 12 me about that. Is there another document 12 submission on TVT-O? 13 that's come out recently specific to your 13 opinions on TVT-O that you were thinking of? A. Yes. Yes. But if they were -- if 14 14 A. The FDA -- and unfortunately, I they were to be manufactured separately 15 15 don't have the binder because it's one of outside of a kit, they would no longer be 16 16 the ones that's with Golkow that I don't considered Class 1. They would be 17 17 18 have back, but there was an advisory 18 considered a Class 2 as part of the 510(k). committee meeting in February of this year 19 Q. Well, actually, have they been 19 20 to discuss and make recommendations whether 20 reclassified? 21 or not to reclassify the instruments that 21 A. No. There's a recommendation. As 22 are used in the insertion of the medical 22 we know, that takes -- that's a process. 23 devices in stress urinary incontinence 23 O. Some time. 24 devices, for example, to reclassify those 24 A. It takes some time. But if, in 25 from Class 1 to Class 2. 25 fact, FDA makes a determination that they Page 35 Page 37 Q. And was that a panel meeting? 1 will reclassify those instruments and they 1 2 2 A. Yes, it was. reclassify them as Class 2, then they become, if I recall correctly, the 3 Q. And were there recommendations made 3 recommendation would be that they would 4 by the panel? 4 5 A. Yes. If I recall correctly, and I 5 require a 510(k) submission. 6 wish I had that document with me, but if I 6 Q. Okay. Does Ethicon sell the instruments separately? Do you know? 7 7 recall correctly, the recommendation was to 8 8 reclassify those insertion instruments, A. As far as I know as regards to those types of medical devices as Class 2. 9 9 TVT-O, they're sold in the kit. 10 Q. All right. Now, how would that, if 10 Q. In the kit. it would, impact the TVT-O and your opinions 11 A. Yeah. 11 12 on TVT-O? O. All right. So just with respect to 12 13 MR. GOSS: Objection. Form. 13 the TVT-O, would I be correct that even if THE WITNESS: They were still those instruments were reclassified as 14 14 15 reviewed, the instruments for insertion 15 Class 2, would that impact TVT-O? for TVT-O were included in the review of A. I think the real point is that the 16 16 instruments-- if I recall correctly -- do the -- in the 510(k). So they were 17 17 18 included in the 510(k), reviewed for 18 you have a copy of the 510(k)? O. I don't. He may. 19 clearance of the TVT-O. 19 20 But the instruments by 20 A. If I recall correctly, I'd have to look specifically in the TVT-O 510(k), but 21 themselves had previously been 21 22 classified as Class 1. When they're 22 many times you will see in the 510(k) that 23 reviewed as a part of the 510(k), then the instruments are discussed as Class 1 23 they're reviewed. Obviously, they were 24 24 devices by the manufacturer. They are 25 included in the 510(k) submission as a 25 reviewed -- when it's -- when they are

	•	Page 38			Page 40
1	submitted as a part of a kit, obviously, a	3	1	A. Oh, I'm sorry.	. 5
2	510(k) has been submitted. The FDA is		2	Q. Were you asked by FDA to be on the	
3	looking at the instruments as a part of the		3	advisory panel?	
	510(k).		4	A. No.	
4			_		
5	So even though they may have been		5	Q. Was there more than one advisory	
6	on their own considered Class 1 devices, the		6	panel or just one?	
7	FDA is looking at them within the framework		7	A. There was for this, my	
8	of the context of a 510(k). I think the		8	understanding it was the latter part of	
9	significance of the finding or the		9	February, and there was, to my knowledge, as	5
10	recommendation, I should say, of the		10	I sit here today, there was one.	
11	advisory committee is that the instruments		11	Q. Okay. And do you know which panel	
12	require more than general controls, if they		12	it was? And I'm sorry I don't have the	
13	require special controls to provide a		13	document in front of me. I just don't know	
14	reasonable assurance of safety and		14	if you recall.	
15	effectiveness which is the criteria to		15	A. Yes. I believe it was had to do	
16	define a Class 2 device, that there are		16	with urology, but I would have to look it	
17	that the instruments themselves, safety and		17	up. As I say, it's in the binder that I	
18	effectiveness issues need to be addressed		18	still don't have back.	
19	for the instruments as well.		19	Q. You keep throwing that out there.	
20			20	Come on. We'll get it back.	
	Q. And so would Ethicon need to do				
21	something different with the TVT-O if those		21	Let me ask you a follow-up on	
22	instruments got reclassified?		22	something you just said. As I understand	
23	A. At this point in time, all I've		23	it, you said the instruments had been	
24	seen that's been published that I've seen is		24	Class 1, and Class 1 are devices for which	
25	the recommendations from the advisory		25	general controls are sufficient	
		Page 39			Page 41
1	committee. Since these were marketed as	Page 39	1	A. Yes.	Page 41
1 2	committee. Since these were marketed as part of the kit, I don't anticipate that,	Page 39	1 2	A. Yes. Q to demonstrate safety and	Page 41
		Page 39			Page 41
2	part of the kit, I don't anticipate that,	Page 39	2	Q to demonstrate safety and	Page 41
2	part of the kit, I don't anticipate that, but I don't know until we see what FDA does,	Page 39	2 3	Q to demonstrate safety and efficacy.	Page 41
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	•	Page 42			Page 44
1	Q. I was going to ask, is that the '99		1	A. 55.	
2	surgical mesh guidance that you're talking		2	Q. 55? I was thinking 77. Is it	
3	about?		3	14155? Which ISO standard is that?	
4	A. Yes. That would be one.		4	A. That is the clinical	
5	Q. That would be one example of a		5	investigations. Which one are you	
6	special control applicable to TVT-O?		6	Q. I was thinking of a different one.	
7	A. That's correct.		7	We'll come to it. All right. I got off my	
8	Q. All right. Are there others		8	outline as I tend to do.	
9	applicable to TVT-O?		9	A. No worries.	
10	A. I would have to look at the		10	Q. Which lawyers are you working for	
11	classification index, for example, certain		11	in this case?	
12	standards like the ISO standards, voluntary		12	A. Mr. Goss.	
13	consensus standards, those can be certain		13	Q. And have you worked for Mr. Goss	
14	types of consensus standards. I need to		14	before?	
15	look at the classification regulation and		15	A. I have.	
16	refresh my memory on that as to whether or		16	Q. About how many cases have you	
17	not there are any of those cited. The key		17	worked with him on?	
18	one, as I recall, is the 1999 guidance		18	A. For mesh?	
19	document.		19	Q. I'll start with for mesh.	
20	Q. Okay. And I'll be candid with you.		20	A. To the best of my recollection	
21	I'm not aware of another special control,		21	Q. You have a list.	
22	but I didn't know if you might know one off		22	A. I have a list. I can actually	
23	the top of your head.		23	verify my memory. At this point in time, it	
	• •				
24	A. Well, in the guidance, in the		24	appears to be five.	
25	March 1999 guidance, I don't have a copy		25	Q. Okay. And I'm glad you pulled that	
		Dago 42			Dago 4E
1	here in front of me, but it discusses	Page 43	1	out. I'm going to mark that actually as	Page 45
1	here in front of me, but it discusses	Page 43	1	out. I'm going to mark that actually as	Page 45
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1 Ayet. 2 Q. Are there so it looks like your 3 deposition testimony ends in November 4 of 2015 on Exhibit 8. 4 of 2015 on Exhibit 8. 5 A. Yes. 6 Q. Is the deposition that I did of you 4 two weeks ago the only deposition that 8 you've given to date in 2016? 9 A. Can I just take a look at that? 10 Q. Oh, sure. 11 A. Time goes so quickly. I have to 12 stop and think. 12 Q. Ohs, sure. 13 Q. Yesh, I know. We're just in March. 14 A. I know. To the best of my 15 recollection, as I sif here today, that's 16 correct. 17 Q. Okay. Just the one I did two weeks 18 ago? 19 A. Yes, that's correct. 20 Q. You can keep that in front of you. 21 I'm going to ask you a few more questions 22 while we're on the topic. 23 In looking at Exhibit 8, are you 24 able to tell me how many times you've 25 testified at trial in a pelvic mesh case?  10 Q. Okay. Nine trials? 2 Q. Now, have you given deposition 2 A. Time. 3 Q. Okay. Nine trials? 4 A. Nine trials. 5 Q. For pelvic mesh? 5 A. Yes. 9 Q. And how many mesh manufacturers has 8 that involved? 9 A. Three. 10 Q. And who are they? 11 A. Three. 12 Estified at trial in a pelvic mesh case? 15 Estimony in cases involving additional products for Pelvic mesh? 3 Q. Clay, Nine trials? 4 A. Yes. 9 Q. And how many mesh manufacturers has 8 that involved? 9 A. Three. 10 Q. And who are they? 11 A. Three. 12 Estified at trial for? 13 Q. All right. 14 A. Tot would include for Bard, the light principally Align. 15 Estimony in cases involving additional products for pelvic mesh? 15 Estimony in cases involving additional products for pelvic mesh? 16 Lettion, Boston Scientific, and the Perfix, which is a sling. 17 A. That would include for Bard, the light products have you think the only other sling about which I have included the Uphold, which is a pelvic organ prolapse device, and the think the only other sling about which I have good of the deposition was Align, but the firm Avaulta was a slos discussed, and my report for Avaulta was a slos discussed, and my report for Avaulta was a slos discussed,		Page 46			Page 48
2 Q. Are there — so it looks like your 3 deposition testimony ends in November 4 of 2015 on Exhibit 8, 5 A. Yes, Q. Is the deposition that I did of you 7 two weeks ago the only deposition that 8 you've given to date in 2016? 9 A. Can I just take a look at that? 10 Q. Oh, sure. 11 A. Time goes so quickly. I have to 12 stop and think. 13 Q. Yeah, I know. We're just in March. 14 A. I know. To the best of my 15 recollection, as I sit here today, that's 16 correct. 17 Q. Okay. Just the one I did two weeks 18 ago? 18 A. Yes, that's correct. 19 Q. You can keep that in front of you. 21 I'm going to ask you a few more questions 22 while we're on the topic. 23 In looking at Exhibit 8, are you 24 able to tell me how many times you've 25 testified at trial in a pelvic mesh case? 25 Q. Now, have you given deposition 26 A. Yes. 27 Q. Okay. Nine trials? 3 Q. Okay. Nine trials? 4 A. Nine trials. 5 Q. For pelvic mesh? 5 A. Yes. 6 Q. And how many mesh manufacturers has that involved? 9 A. Three. 19 Q. And who are they? 10 Q. All right. 10 Q. Is align a sling or a prolapse? 11 A. R Sa a sling. 20 Q. Is align a sling or a prolapse? 12 A. Tris a sling. 13 Q. Okay. 14 C. It's a prolapse? 15 where you've testified at trial, am I right that it's the Align, the TVT-O, Obtryx, and that it's the Align, the TVT-O, Obtryx, and that was a trial? 16 to that it's the Align, the TVT-O, Obtryx, and that was a trial? 17 the Abbrevo? 18 A. Yes. And also for Boston 19 Scientific and the Scherer trial, it also included the Solyx. 20 (D. Kay. Nine trials? 21 A. Yes. It's a single-incision sling. 22 A. Yes. It's a single-incision sling. 23 Q. Okay. And that was a trial? 24 A. Yes. 25 Q. Now, have you given deposition 26 Vestiments? 27 Q. And how many mesh manufacturers has that involved? 28 A. Three. 39 Q. And who are they? 30 Q. And who are they? 31 A. R Sa a sling. 31 A. Oka Bard. 32 Q. Okay. So on additional products in deposition restimony for Bard? 32 Q. Okay. 33 A. Bard. 34 D. The deposition was Align, but the three of Avaulta was also incorpor	1		1	A. TVT-O?	
3 A. Batiste. Batiste. I think 4 of 2015 on Exhibit 8. 5 A. Yes. 6 Q. Is the deposition that I did of you two weeks ago the only deposition that 8 you've given to date in 2016? 9 A. Can I just take a look at that? 10 Q. Oh, sure. 11 A. Time goes so quickly. I have to 12 stop and think. 13 Q. Yeah, I know. We're just in March. 14 A. I know. To the best of my 15 recollection, as I sit here today, that's 16 correct. 17 Q. Okay. Just the one I did two weeks 18 ago? 19 A. Yes, that's correct. 20 Q. You can keep that in front of you. 21 I'm going to ask you a few more questions 22 while we're on the topic. 23 In looking at Exhibit 8, are you 34 able to tell me how many times you've 4 testified at trial in a pelvic mesh case? 4 A. I believe it's nine but just let me 2 check that. Yes, nine. 4 A. I believe it's nine but just let me 2 check that. Yes, nine. 5 Q. And who are they? 6 A. Yes. 6 A. Yes. 7 Q. And who are they? 1 A. Time. 9 Q. And who are they? 1 A. Three. 1 Q. And who are they? 1 A. Three. 1 Q. And who are they? 1 A. Three. 1 Q. And who are they? 1 A. The wold include for Bard, the 1 Staffing. 1 Staffing. 1 Staff as ling. 2 D. Okay. 2 D. Skalgn a sling or a prolapse? 2 A. Yes. For Boston Scientific, it 2 bard. 3 A. Res. 4 A. Ok. 2 D. Skapan. 3 A. Rasiste. Havink 4 that's – those are the products for 5 Ethicon, and then for Boston Scientific, it 6 would have been Obtryx. 9 Q. Is that a sling? 9 Q. Is flat a sling? 9 Q. Is flat a sling. 1 Staff a playic corgan prolapse 1 A. No. 1 Staff a plevic organ prolapse 1 Staff a plevic organ prolapse 2 A. Yes. Or Staff a plevic organ prolapse 2 A. No. 3 Gevice.  9 Q. Not where you've testified at trial, am I right 6 that it's the Align, the TVT-O, Obtryx, and 17 the Abbrevo? 18 A. Yes. And also for Boston 19 Scientific and the Scherer trial, it also 10 Included the Solyx. 21 Q. Is that a sling? 22 Q. Okay. Nine trials? 23 Q. Okay. Nine trials? 3 Q. Okay. Nine trials? 4 A. Yes. 5 Q. Okay. Nine trials? 5 Q. Or And who are they? 6 A. Yes. 7 Q. And who are they? 8 A. Three.					
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5 A. Yes. 6 Q. Is the deposition that I did of you to weeks ago the only deposition that 3 you've given to date in 2016? 7 Q. Oh, sure. 10 Q. Oh, sure. 11 A. Time goes so quickly. I have to 11 Q. Step and think. 12 Stop and think. 13 Q. Yeah, I know. We're just in March. 14 A. I know. To the best of my 15 recollection, as I sit here today, that's correct. 15 recollection, as I sit here today, that's correct. 16 Q. Okay. Just the one I did two weeks ago					
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10 Q. Oh, sure. 11 A. Time goes so quickly. I have to 12 stop and think. 13 Q. Yeah, I know. We're just in March. 14 A. I know. To the best of my 15 recollection, as I sit here today, that's 16 correct. 17 Q. Okay. Just the one I did two weeks 18 ago? 18 A. Yes, that's correct. 19 A. Yes, that's correct. 19 Q. You can keep that in front of you. 21 I'm going to ask you a few more questions 22 while we're on the topic. 23 In looking at Exhibit 8, are you 24 able to tell me how many times you've 25 testified at trial in a pelvic mesh case? 26 Q. You Can keep that in front of you. 27 I'm going to ask you a few more questions 28 while we're on the topic. 29 A. Yes. It's a single-incision sling. 20 Q. Al res. It's a single-incision sling. 21 A. I believe it's nine but just let me 22 check that. Yes, nine. 23 Q. Okay. Nine trials. 24 A. Nine trials. 25 Q. For pelvic mesh? 26 A. Yes. 27 Q. And how many mesh manufacturers has that involved? 38 A. Yes. 49 A. Time. 40 Q. All right. So for sling cases 40 Where you've testified at trial, am I right 41 A. I shaling, the TVT-O, Obtryx, and 42 A. Yes. And also for Boston 42 Scientific and the Scherer trial, it also 41 included the Solyx. 41 I'm going to ask you a few more questions 42 A. Yes. Are s sling? 43 A. Yes. 44 A. Yes. 45 Q. Okay. Nine trials? 46 A. Nine trials. 47 Q. Okay. Nine trials? 48 A. Nine trials. 49 Q. Can you tell me what those are? 50 Q. For pelvic mesh? 51 A. Ethicon, Boston Scientific, and 52 A. Yes. For Boston Scientific, that 53 Walle we're on the topy of the sting about which I 54 A. CR Bard. 55 Q. All right. 56 A. CR Bard. 57 Q. All right. 58 A. Yes. 59 A. Yes. For Boston Scientific, that 50 Q. Okay. Nine trials? 50 Q. All right. 51 A. Time. 52 Q. All right. 53 A. Yes. 54 A. Yes. 55 Q. Now, have you given deposition 55 Q. Okay. Nine trials. 56 Q. Okay. Nine trials. 57 Q. Okay. Nine trials. 58 A. Yes. 59 A. Yes. Tres abingle-incision sling. 50 Q. For pelvic mesh? 50 Q. Okay. Nine trials. 51 Lestimony in cases involving additional 51 testimony in cases i		,			
11 A. Time goes so quickly. I have to stop and think.  12 stop and think.  13 Q. Yeah, I know. We're just in March.  14 A. I know. To the best of my secolicition, as I sit here today, that's recollection, as I sit here today, that's correct.  15 recollection, as I sit here today, that's sago?  16 Q. Okay. Just the one I did two weeks ago with the Abbrevo?  17 Q. Okay. Just the one I did two weeks ago with the Abbrevo?  18 ago?  19 A. Yes, that's correct.  10 Q. You can keep that in front of you.  21 I'm going to ask you a few more questions will we're on the topic.  22 while we're on the topic.  23 In looking at Exhibit 8, are you as leve testified at trial in a pelvic mesh case?  24 able to tell me how many times you've testified at trial in a pelvic mesh case?  25 testified at trial in a pelvic mesh case?  26 Q. Now, have you given deposition  Page 47  1 A. I believe it's nine but just let me check that. Yes, nine.  2 Q. Okay. Nine trials?  3 Q. Okay. Nine trials?  4 A. Nine trials.  5 Q. For pelvic mesh?  5 Q. For pelvic mesh?  6 A. Yes.  7 Q. And how many mesh manufacturers has that involved?  8 A. Three.  9 A. Three.  9 And for Ethicon, we already addressed Prolift and Prosima. So those are the two pelvic organ prolapse devices. I think the only other sling about which I have given deposition testimony is TVT from Ethicon.  16 A. CR Bard.  17 A. That would include for Bard, the align. Discussion about Avaulta came up, but it was principally Align.  18 A. CR Bard.  19 A. That would include for Bard, the align. Discussion about Avaulta came up, but it was principally Align.  20 Q. Okay.  21 A. Tis a sling.  22 A. Yes.  23 A. Yes.  24 A. Title Align. Discussion about Avaulta came up, but it was principally Align.  25 D. Cary or and the products in deposition testimony for Bard?  26 A. A. A. A. That would include for Bard, the align. Discussion about Avaulta came up, but it was principally Align.  26 A. A. A. A. That would include for Bard, the align. Discussion about Avaulta came up, but it was principally Al					
stop and think. Q. Yeah, I know. We're just in March. 13 device. 14 A. I know. To the best of my 15 recollection, as I sit here today, that's 16 correct. 17 Q. Okay. Just the one I did two weeks 18 ago? 18 ago? 19 A. Yes, that's correct. 19 Scientific and the Scherer trial, it also 17 g. You can keep that in front of you. 20 I'm going to ask you a few more questions 21 I'm going to ask you a few more questions 22 while we're on the topic. 23 In looking at Exhibit 8, are you 24 able to tell me how many times you've 25 testified at trial in a pelvic mesh case? 26 check that. Yes, nine. 27 check that. Yes, nine. 28 d. A. Nine trials. 29 d. A. Nine trials. 30 Q. Okay. Nine trials? 4 A. Nine trials. 4 A. Nine trials. 5 Q. For pelvic mesh? 6 A. Yes. 7 Q. And how many mesh manufacturers has that involved? 9 A. Three. 10 Q. And who are they? 11 A. Ethicon, Boston Scientific, and 12 bard. 13 d. Q. All right. 13 d. Q. Weight grade in the set of my 14 that it's the Align, the TVT-O, Obtryx, and 15 that it's the Align, the TVT-O, Obtryx, and 16 that it's the Align, the TVT-O, Obtryx, and 17 the Abbrevo? 18 ago? 18 A. Yes. And also for Boston 19 Cientific and the Scherer trial, it also 19 included the Solyx. 21 Q. Is that a sling? 22 A. Yes. It's a single-incision sling. 23 Q. Now, have you given deposition 24 A. Yes. 25 Q. Now, have you given deposition 25 Q. For pelvic mesh? 26 Q. Okay. Nine trials? 27 Q. Okay Nine trials? 28 A. Yes. For Boston Scientific, that 29 A. Three. 20 Q. And how many mesh manufacturers has that involved? 30 A. Yes. 31 A. Yes. 42 Q. Can you tell me what those are? 43 A. There. 44 Q. Can you tell me what those are? 45 A. Yes. For Boston Scientific, that 46 would have included the Uphold, which is a pelvic organ prolapse device, and the Perfix, which is a sling. 47 Prolift in the TVT-O, Okay. 48 The Abbrevo? 48 The Abbrevo? 49 A. Three. 40 Q. All right. 41 A. CR Bard. 42 Prolift in the Tvarious trial, it also included the very all the two pelvic organ prolapse device. 41 The two pelvic organ prolaps					
device.  14 A. I know. To the best of my recollection, as I sit here today, that's that life that it sit he Align, but that it's the Align, but recollection, as I sit here today, that's a sling.  2. A. Yes. And also for Boston Scientific and the Scherer trial, it also included the Solyx.  2. I cluded the Solyx.  2. Q. Is that a sling?  2. A. Yes. It's a single-incision sling. 2. O. Nay, And that was a trial?  4. A. Yes. 2. O. Now, have you given deposition  Page 49  1. A. I believe it's nine but just let me 2. Check that. Yes, nine. 2. Page 47  1. A. I believe it's nine but just let me 2. Check that. Yes, nine. 2. Page 47  1. A. I believe it's nine but just let me 2. Check that. Yes, nine. 2. Check that. Yes, nine. 2. Check that. Yes, on products for pelvic mesh? 3. A. Yes. 3. A. Yes. 4. A. Nine trials. 4. A. Yes. 5. Can you tell me what those are? 5. A. Yes. For Boston Scientific, that 6. Would have included the Uphold, which is a pelvic o				= ' '	
14 Å I know. To the best of my 15 recollection, as I sit here today, that's 16 correct. 17 Q. Okay. Just the one I did two weeks 18 ago? 18 ago? 19 A. Yes, that's correct. 19 Scientific and the Scherer trial, it also 17 I'm going to ask you a few more questions 18 I looking at Exhibit 8, are you 19 alte to tell me how many times you've 19 testified at trial in a pelvic mesh case? 19 A. Nine trials. 10 Q. Okay. Nine trials. 21 A. Nine trials. 22 Q. Cany ou tell me what those are? 23 Q. And how many mesh manufacturers has 24 A. Nine trials. 25 Q. And how many mesh manufacturers has 26 that involved? 27 Q. And whoh are they? 28 A. Three. 29 A. Three. 30 Q. And whoh are they? 40 Q. And whoh are they? 41 A. CR Bard. 42 A. CR Bard. 43 Q. Al right. 44 A. Q. And whoh products have you 45 testified at trial for? 45 Q. Is align a sling or a prolapse? 46 A. Three. 47 Q. And which products have you 48 testified at trial for? 49 A. Three. 40 Q. And which products have you 49 testified at trial for? 40 A. That would include for Bard, the 41 A. It's a sling or a prolapse? 42 A. It's a sling or a prolapse? 43 A. It's a sling or a prolapse? 44 A. It's a sling or a prolapse? 45 A. It's a sling or a prolapse? 46 A. No. A. I mentioned, I had an Avaulta report which was a big incurpor and my 47 Prolift, Prosima, TVT Abbrevo, TVT-O. 48 Prolift, Prosima, TVT Abbrevo, TVT-O. 49 Prolift, Prosima, TVT Abbrevo, TVT-O. 40 Prolift, Prosima, TVT Abbrevo, TVT-O. 41 Prolift, Prosima, TVT Abbrevo, TVT-O. 41 Prolift, Prosima, TVT Abbrevo, TVT-O. 41 Prolift was principally align. 42 Prolift, Prosima, TVT Abbrevo, TVT-O. 41 Prolift, Prosima, TVT Abbrevo, TVT-O. 42 Prolift, Prosima, TVT Abbrevo, TVT-O. 44 Prolift, Prosima, TVT Abbrevo, TVT-O. 45 Prolift and Prosima, and trial, that it was principally Align. 46 Prolift and Prosima. So those are the two pelvic organ prolapse devices. I think the only other sling about which I have given deposition testimony is TVT from the think the only other sling about which I have given deposition testimony is T		•			
15 recollection, as I sit here today, that's 16 correct. 17 Q. Okay. Just the one I did two weeks 18 ago? 18 ago? 19 A. Yes, that's correct. 20 Q. You can keep that in front of you. 21 I'm going to ask you a few more questions 22 while we're on the topic. 23 In looking at Exhibit 8, are you 24 able to tell me how many times you've 25 testified at trial in a pelvic mesh case? 26 Q. Okay. Nine trials? 27 Q. Okay. Nine trials? 28 A. I believe it's nine but just let me 29 check that. Yes, nine. 20 Q. Okay. Nine trials? 31 Q. Okay. Nine trials? 42 A. Nine trials. 43 A. Yes. 44 A. Nine trials. 55 Q. For pelvic mesh? 65 A. Yes. 66 A. Yes. 67 Q. And how many mesh manufacturers has 68 that involved? 68 A. Three. 69 Q. And who are they? 60 Q. And who are they? 61 A. Ethicon, Boston Scientific, and 63 D. All right. 64 A. CR Bard. 65 Q. And who products have you 66 testified at trial for? 67 A. That would include for Bard, the 68 A. Cr Bard. 69 A. That would include for Bard, the 69 A. That would include for Bard, the 60 A. Are sard. 61 A. It's a sling. 61 A. It's a sling or a prolapse? 62 Q. Okay. 63 A. Ares. 64 A. Ares. 65 Q. And who are they? 66 A. Three. 67 Q. And who are they? 68 Prefix, which is a sling. 69 A. Three. 70 Q. And who are they? 71 A. CR Bard. 71 A. That would include for Bard, the 72 A. That would include for Bard, the 73 Q. And which products have you 74 A. That would include for Bard, the 75 Q. And which products have you 75 Q. Okay. 76 A. That would include for Bard, the 76 A. That would include for Bard, the 77 A. That would include for Bard, the 78 A. It's a sling. 79 Q. Okay. 70 Q. Okay. 71 A. That would include for Bard, the 79 A. Three would have principally Align. 70 Q. Okay. 71 A. That would include for Bard, the 71 A. It's a sling. 72 Q. Okay. 73 A. And for Ethicon, it's included 74 A. It's a sling. 75 A. That would include for Bard, the 76 A. Are the two pelvic organ prolapse devices. I think the only other sling about which I have given deposition testimony for Bard? 76 Q. Okay. 77 A. That w					
16 correct. 17 Q. Okay. Just the one I did two weeks 18 ago? 18 A. Yes, that's correct. 19 A. Yes, that's correct. 19 A. Yes, that's correct. 20 Q. You can keep that in front of you. 21 I'm going to ask you a few more questions 22 while we're on the topic. 23 In looking at Exhibit 8, are you 24 able to tell me how many times you've 25 testified at trial in a pelvic mesh case? 26 Leck that. Yes, nine. 27 Q. Okay. Nane trials? 28 A. Yes. 29 Q. Now, have you given deposition 29 Page 47 20 Lestimony in cases involving additional 20 products for pelvic mesh? 21 Prospired the Uphold, which is a 22 products for pelvic mesh? 23 Q. Okay. Nane trials? 24 A. Yes. 25 Q. Can you tell me what those are? 26 A. Yes. 27 Q. And how many mesh manufacturers has 28 that involved? 39 A. Three. 40 Q. And who are they? 41 A. Thee. 42 Q. And who are they? 43 A. Yes. 44 A. Three. 45 D. And who are they? 46 A. Three. 47 Q. And who are they? 48 D. And who are they? 49 A. Three. 50 Q. And which products have you 51 Estifical at trial for? 51 Esticon. 52 Q. All right. 53 A. Yes. 54 A. Yes. For Boston Scientific, and 55 Q. And which products have you 56 testified at trial for? 57 Q. All right. 58 A. Yes. 59 A. Three. 90 And who are they? 10 Q. And which products have you 11 A. CR Bard. 12 Esticon. 13 Q. Okay. 14 A. CR Bard. 15 D. A. That would include for Bard, the 16 A. It's a sling. 17 A. That would include for Bard, the 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 20 Q. Okay. 21 A. Yes. And that excharge trial and an Avaulta report which was the focus of the 21 A. It's a sling. 22 A. Yes. And that prosima. So those are 23 the two pelvic organ prolapse devices. In think the only other sling about which I have given deposition testimony is TVT from 24 Estifical at trial for? 25 D. Okay. 26 A. And then we've already addressed 27 A. Yes. 28 Bard. 29 A. That would include for Bard, the 29 And for Ethicon, it's included 20 A. No. As I mentioned, I had an Avaulta report which was the focus of the 29 And for	14	A. I know. To the best of my	14	Q. All right. So for sling cases	
17 Q. Okay. Just the one I did two weeks ago? 18 ago? 19 A. Yes, that's correct. 19 Q. You can keep that in front of you. 21 I'm going to ask you a few more questions 22 while we're on the topic. 23 In looking at Exhibit 8, are you 24 able to tell me how many times you've 25 testified at trial in a pelvic mesh case? 26 La A. I believe it's nine but just let me 27 check that. Yes, nine. 28 Q. Okay. Nine trials? 3 Q. Okay. Nine trials? 4 A. Nine trials. 4 Q. Can you tell me what those are? 5 Q. For pelvic mesh? 5 Q. For pelvic mesh? 6 A. Yes. 7 Q. And how many mesh manufacturers has 8 that involved? 9 A. Three. 9 A. Three. 9 A. Three. 10 Q. And who are they? 11 A. Ethicon, Boston Scientific, and 12 Bard. 13 Q. All right. 14 A. CR Bard. 15 Q. And which products have you 16 testified at trial for? 17 A. That would include for Bard, the 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 10 Q. Okay. 21 L'm Aad for Ethicon, it's included 22 A. Yes. 23 Q. Okay. So no additional products in deposition necessary. 24 A. Yes. 25 Q. Okay. 26 A. Yes. 27 Q. Okay. 28 A. Yes. 29 And which products have you 29 Q. Sa Align a sling or a prolapse? 20 Q. Skay. 21 Q. Okay. 21 L'm ad also for Boston 20 included the Solyx. 21 Q. Is that a sling? 22 A. Yes. It's a single-incision sling. 23 Q. Okay. And that was a trial? 24 A. Yes. 25 Q. Now, have you given deposition 29 Prolify in cases involving additional products in deposition testimony in cases involving additional products in deposition testimony is TVT from tent the two pelvic organ prolapse devices. I hink the only other sling about which I alian have given deposition testimony is TVT from tent the two pelvic organ prolapse devices. I hink the only other sling about which I alian have given deposition testimony is TVT from tent the two pelvic organ prolapse devices. I hink the only other sling about which I alian have given deposition testimony is TVT from tent the two pelvic organ prolapse devices. I hink the only other sling about which I alian have gi	15	recollection, as I sit here today, that's	15	where you've testified at trial, am I right	
18 ago? A. Yes, that's correct. 19 A. Yes, that's correct. 20 Q. You can keep that in front of you. 21 I'm going to ask you a few more questions 22 while we're on the topic. 23 In looking at Exhibit 8, are you 24 able to tell me how many times you've 25 testified at trial in a pelvic mesh case? 26 A. I believe it's nine but just let me 27 check that. Yes, nine. 28 Q. Okay. Nine trials? 3 Q. Okay. Nine trials? 4 A. Nine trials. 4 A. Nine trials. 5 Q. For pelvic mesh? 6 A. Yes. 7 Q. And how many mesh manufacturers has 8 that involved? 9 A. Three. 10 Q. And who are they? 11 A. Ethicon, Boston Scientific, and 11 Estificed at trial for? 12 Bard. 13 Q. All right. 14 A. CR Bard. 15 Q. And which products have you 16 testified at trial for? 16 A. That would include for Bard, the 17 A. Int was principally Align. 18 A. Yes. And also for Boston 20 included the Solyax. 21 Q. Is that a sling? 22 A. Yes. It's a single-incision sling. 23 Q. Okay. And that was a trial? 24 A. Yes. 25 Q. Now, have you given deposition 26 Page 47 27 A. Yes. 28 Products for pelvic mesh? 29 A. Yes. 20 Can you tell me what those are? 30 A. Yes. For Boston Scientific, that 40 Would have included the Uphold, which is a pelvic organ prolapse device, and the 41 Prolift and Prosima. So those are 42 the two pelvic organ prolapse devices. I think the only other sling about which I also we prolapse devices. I the two pelvic organ prolapse devices. I the two pelvic organ prolapse devices. I the two pelvic organ prolapse devices. I think the only other sling about which I also we prolapse devices. I the two pelvic organ prolapse devices. I the two pelvic org	16	correct.	16	that it's the Align, the TVT-O, Obtryx, and	
19 A. Yes, that's correct. 20 Q. You can keep that his front of you. 21 I'm going to ask you a few more questions 22 while we're on the topic. 23 In looking at Exhibit 8, are you 24 able to tell me how many times you've 25 testified at trial in a pelvic mesh case? 26 Lestified at trial in a pelvic mesh case? 27 Q. Okay. And that was a trial? 28 A. Yes. It's a single-incision sling. 29 Q. Okay. And that was a trial? 20 Q. Now, have you given deposition 29 A. Yes. 20 Page 47 21 A. I believe it's nine but just let me 22 check that. Yes, nine. 23 Q. Okay. Nine trials? 31 Q. Okay. Nine trials? 42 A. Yes. 43 A. Nine trials. 44 A. Nine trials. 45 Q. For pelvic mesh? 46 A. Yes. 47 Q. And how many mesh manufacturers has that involved? 48 that involved? 49 A. Three. 40 Q. And who are they? 40 And who are they? 41 A. Ethicon, Boston Scientific, and 41 A. Ethicon, Boston Scientific, and 41 A. C. R. Bard. 42 A. C. R. Bard. 43 Q. And which products have you 44 A. C. R. Bard. 45 Q. And which products have you 46 Estified at trial for? 46 A. C. R. Bard. 47 A. That would include for Bard, the 48 Align. Discussion about Avaulta came up, 49 but it was principally Align. 40 Q. Okay. 41 A. Oka J. T. Bard. 41 A. C. R. Bard. 42 Q. Okay. 43 And for Ethicon, it's included 44 A. C. R. Bard. 45 Q. Okay. 46 And then we've already addressed 47 A. That would include for Bard, the 48 Align. Discussion about Avaulta came up, 49 but it was principally Align. 40 Q. Okay. 41 A. And then we've already addressed 41 A. C. R. Bard. 42 Q. Okay. 43 And for Ethicon, it's included 44 A. C. R. G. Sain. 45 Bard. 46 A. C. R. G. Sain. 47 Bard. 48 A. C. R. Bard. 49 C. Okay. 40 C. Okay. 41 A. C. R. Bard. 41 Ethicon. 41 Bard. 42 C. Okay. 43 A. C. R. Bard. 43 C. Okay. 44 C. R. Bard. 45 Bard. 46 C. Okay. 47 A. C. R. Bard. 48 Bard. 49 C. Okay. 40 C. Okay. 41 A. C. R. Bard. 40 C. Okay. 41 A. C. Okay. 42 Prolift, Prosima, TVT Abbrevo, TVT-O. 41 A. C. R. G. C.	17	Q. Okay. Just the one I did two weeks	17	the Abbrevo?	
A. Yes, that's correct. Q. You can keep that in front of you. 20 included the Solyx. 21 I'm going to ask you a few more questions 22 while we're on the topic. 23 In looking at Exhibit 8, are you 24 able to tell me how many times you've 25 testified at trial in a pelvic mesh case? 26 Lestified at trial in a pelvic mesh case? 27 Q. Now, have you given deposition 28 A. I believe it's nine but just let me 2 check that. Yes, nine. 3 Q. Okay. Nine trials? 4 A. Nine trials. 5 Q. For pelvic mesh? 6 A. Yes. Q. And how many mesh manufacturers has 8 that involved? 9 A. Three. 9 And how many mesh manufacturers has 8 that involved? 9 A. Three. 10 Q. And who are they? 11 A. Ethicon, Boston Scientific, and 12 Bard. 13 Q. All right. 14 A. CR Bard. 15 Q. And which products have you 16 testified at trial for? 17 Bard. 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 20 Okay. 21 A. Yes. It's a sing? 22 A. Yes. It's a single-incision sling. 22 A. Yes. It's a single-incision sling. 23 Q. Okay. And that was a trial? 24 A. Yes. 25 Q. Now, have you given deposition 26 testified at trial in a pelvic mesh case? 27 Q. Now, have you given deposition all testimony in cases involving additional products for pelvic mesh? 3 A. Yes. 4 Q. Can you tell me what those are? 4 Q. Can you tell me what those are? 5 A. Yes. For Boston Scientific, that 6 would have included the Uphold, which is a pelvic organ prolapse device, and the 8 Prefix, which is a sling. 9 And for Ethicon, we already addressed Prolifit and Prosima. So those are 11 the two pelvic organ prolapse devices. I 12 think the only other sling about which I 13 have given deposition testimony is TVT from 14 A. CR Bard. 15 Q. Okay. 16 testified at trial for? 17 A. That would include for Bard, the 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 19 deposition testimony for Bard? 20 Q. Is Align a sling or a prolapse? 21 A. No. As I mentioned, I had an 22 A. No. As I mentioned, I had an 23 A. Yes. 24 H. Yes. 25 Q. Okay. 25 Can you tell me	18	ago?	18	A. Yes. And also for Boston	
Q. You can keep that in front of you. I'm going to ask you a few more questions while we're on the topic. In looking at Exhibit 8, are you able to tell me how many times you've testified at trial in a pelvic mesh case?  Page 47  A. I believe it's nine but just let me check that. Yes, nine. Q. Okay. Nine trials? A. Nine trials. Q. Okay. Nine trials. Q. Oray. Nine trials. A. Yes. C. Search white that was a trial? A. Yes. C. Q. Now, have you given deposition  Page 49  1 testimony in cases involving additional products for pelvic mesh? A. Yes. C. Can you tell me what those are? A. Yes. For Boston Scientific, that C. Would have included the Uphold, which is a pelvic organ prolapse device, and the that involved? A. Three. Q. And who are they? A. Ethicon, Boston Scientific, and A. CR Bard. Q. All right. A. CR Bard. Q. And which products have you testified at trial for? A. That would include for Bard, the Align. Discussion about Avaulta came up, but it was principally Align. Q. Okay. A. And for Ethicon, it's included A	19		19	Scientific and the Scherer trial, it also	
21 I'm going to ask you a few more questions 22 while we're on the topic. 23 In looking at Exhibit 8, are you 24 able to tell me how many times you've 25 testified at trial in a pelvic mesh case? 26 Q. Now, have you given deposition  Page 47  A. I believe it's nine but just let me 2 check that. Yes, nine. 2 Q. Okay. Nine trials? 3 Q. Okay. Nine trials? 4 A. Nine trials. 4 Q. Can you tell me what those are? 4 A. Yes. 5 Q. For pelvic mesh? 5 Q. For pelvic mesh? 6 A. Yes. 7 Q. And how many mesh manufacturers has 8 that involved? 8 that involved? 9 A. Three. 1 Q. And who are they? 1 0 And who are they? 1 1 believe it's nine but just let me 1 testimony in cases involving additional products for pelvic mesh? 3 A. Yes. 4 Q. Can you tell me what those are? 4 A. Yes. For Boston Scientific, that would have included the Uphold, which is a pelvic organ prolapse device, and the 8 that involved? 9 A. Three. 9 And for Ethicon, we already 10 dersesed Prolift and Prosima. So those are 11 think the only other sling about which I have given deposition testimony is TVT from 14 A. CR Bard. 15 Q. All right. 16 A. CR Bard. 17 A. That would include for Bard, the 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 20 Q. Is Align a sling or a prolapse? 21 A. And for Ethicon, it's included 22 Q. Okay. 23 A. And for Ethicon, it's included 24 Prolift, Prosima, TVT Abbrevo, TVT-O. 24 report for Avaulta was also incorporated in	20				
while we're on the topic. In looking at Exhibit 8, are you able to tell me how many times you've testified at trial in a pelvic mesh case?  Page 47  A. I believe it's nine but just let me check that. Yes, nine. Q. Okay. Nine trials? A. Nine trials? A. Nine trials? A. Nine trials? A. Yes. Q. Can you tell me what those are? A. Yes. Can you tell me what those are? A. Yes. Q. Can you tell me what those are? A. Yes.				•	
In looking at Exhibit 8, are you able to tell me how many times you've testified at trial in a pelvic mesh case?  Page 47  A. I believe it's nine but just let me check that. Yes, nine.  Q. Okay. Nine trials?  A. Nine trials.  A. Nine trials.  A. Nine trials.  A. Nine trials.  A. Yes.  Output mesh?  A. Yes.  A. Nine trials.  A. Yes.  A. Yes. For Boston Scientific, that would have included the Uphold, which is a sling.  A. Three.  A. Ethicon, Boston Scientific, and  Bard.  A. CR Bard.  A. CR Bard.  A. CR Bard.  A. That would include for Bard, the Align. Discussion about Avaulta came up, but it was principally Align.  A. It's a sling.  Q. Okay.  A. And for Ethicon, it's included  A. Fes.  A. And for Ethicon, it					
24 able to tell me how many times you've testified at trial in a pelvic mesh case?  Page 47  A. I believe it's nine but just let me check that. Yes, nine.  Q. Okay. Nine trials?  A. Nine trials.  Q. For pelvic mesh?  A. Yes.  Q. For pelvic mesh?  A. Yes.  Q. For pelvic mesh?  A. Yes.  Q. And how many mesh manufacturers has that involved?  A. Three.  Q. And who are they?  A. Ethicon, Boston Scientific, and  D. And which products for pelvic mesh average device, and the prefix, which is a sling.  A. Three.  A. Res.  A. Three.  A. Three.  A. Three.  A. And for Ethicon, we already addressed Prolift and Prosima. So those are the two pelvic organ prolapse devices. I think the only other sling about which I have given deposition testimony is TVT from Ethicon.  A. That would include for Bard, the Align. Discussion about Avaulta came up, but it was principally Align.  A. It's a sling.  A. It's a sling.  A. And for Ethicon, it's included  A. And for Ethicon, we already addressed Bard.  A. Cokay.  A. And then we've already addressed  Bard.  A. Okay. So no additional products in deposition testimony for Bard?  A. No. As I mentioned, I had an  Avaulta report which was the focus of the  the focus of the deposition was Align, but their Avaulta was also discussed, and my report for Avaulta was also discussed, and my report for Avaulta was also incorporated in		·			
25 Lestified at trial in a pelvic mesh case?  Page 47  1 A. I believe it's nine but just let me 2 check that. Yes, nine. 3 Q. Okay. Nine trials? 4 A. Nine trials. 5 Q. For pelvic mesh? 6 A. Yes. 7 Q. And how many mesh manufacturers has 8 that involved? 9 A. Three. 9 A. Ethicon, Boston Scientific, and 11 Etestimony in cases involving additional 2 products for pelvic mesh? 3 A. Yes. 4 Q. Can you tell me what those are? 4 A. Yes. For poston Scientific, that 4 would have included the Uphold, which is a 8 pelvic organ prolapse device, and the 9 Prefix, which is a sling. 9 And for Ethicon, we already 10 Q. And who are they? 11 A. Ethicon, Boston Scientific, and 11 think the only other sling about which I 12 think the only other sling about which I 13 Q. All right. 14 Ethicon. 15 Q. And which products have you 16 testified at trial for? 16 A. And then we've already addressed 17 A. That would include for Bard, the 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 19 but it was principally Align. 20 Q. Is Align a sling or a prolapse? 21 A. It's a sling. 22 Q. Okay. 23 A. And for Ethicon, it's included 24 Prolift, Prosima, TVT Abbrevo, TVT-O. 25 Q. Ovay. 26 Progret or Avaulta was also incorporated in					
Page 47  A. I believe it's nine but just let me check that. Yes, nine.  Q. Okay. Nine trials?  A. Nine trials.  A. Nine trials.  Q. For pelvic mesh?  A. Yes.  Q. Can you tell me what those are?  A. Yes. For Boston Scientific, that  would have included the Uphold, which is a pelvic organ prolapse device, and the prefix, which is a sling.  A. Three.  Q. And who are they?  A. Ethicon, Boston Scientific, and  A. CR Bard.  Q. And which products have you testified at trial for?  A. That would include for Bard, the Align. Discussion about Avaulta came up, but it was principally Align.  Q. Is Align a sling or a prolapse?  Q. Okay.  A. And for Ethicon, we already addressed Prolift and Prosima. So those are the two pelvic organ prolapse devices. I the two pelvic organ prolapse device, and the prefix, which is a sling.  And for Ethicon, we already addressed Prolift and Prosima. So those are the two pelvic organ prolapse devices. I the two pelvic organ prolapse device, and the Prefix, which is a sling.  And for Ethicon, we already addressed Prolift and Prosima. So those are the two pelvic organ prolapse devices. I the two pelvic organ pro		·			
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2 check that. Yes, nine. 3 Q. Okay. Nine trials? 4 A. Nine trials. 5 Q. For pelvic mesh? 6 A. Yes. 7 Q. And how many mesh manufacturers has 8 that involved? 9 A. Three. 10 Q. And who are they? 11 A. Ethicon, Boston Scientific, and 12 Bard. 13 Q. All right. 14 A. CR Bard. 15 Q. And which products have you 16 testified at trial for? 17 A. That would include for Bard, the 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 20 Okay. 21 A. It's a sling. 21 A. And for Ethicon, it's included 22 Products for pelvic mesh? 3 A. Yes. 4 Q. Can you tell me what those are? 5 A. Yes. 6 would have included the Uphold, which is a sling. 7 pelvic organ prolapse device, and the 8 Prefix, which is a sling. 9 And for Ethicon, we already addressed Prolift and Prosima. So those are 11 the two pelvic organ prolapse devices. I 11 think the only other sling about which I 12 have given deposition testimony is TVT from 14 A. CR Bard. 15 Q. Okay. 16 A. And then we've already addressed 17 Bard. 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 19 deposition testimony for Bard? 20 A. No. As I mentioned, I had an 21 A. It's a sling. 21 Avaulta report which was the focus of the 22 Q. Okay. 23 A. And for Ethicon, it's included 24 Prolift, Prosima, TVT Abbrevo, TVT-O. 25 Products for you tell me what those are? 26 A. Yes. 27 A. Yes. 28 A. Yes. 4 Q. Can you tell me what those are? 5 A. Yes. 6 would have included the Uphold, which is a 9 Prefix, which is a sling. 7 pelvic organ prolapse device, and the 9 Prefix, which is a sling. 7 pelvic organ prolapse device, and the 9 Prefix, which is a sling. 7 pelvic organ prolapse device, and the 9 Prefix, which is a sling. 9 And for Ethicon, we already 10 addressed Prolift and Prosima. So those are 11 think the only other sling about which I 12 think the only other sling about which I 13 have given deposition testimony is TVT from 16 A. And then we've already addressed 17 A. And then we've already addressed 18 A. And then we've already addressed 19 A. A		Page 47			Dago 40
3 A. Yes. 4 A. Nine trials. 5 Q. For pelvic mesh? 6 A. Yes. 7 Q. And how many mesh manufacturers has 8 that involved? 9 A. Three. 10 Q. And who are they? 11 A. Ethicon, Boston Scientific, and 12 Bard. 13 Q. All right. 14 A. CR Bard. 15 Q. And which products have you 16 testified at trial for? 17 A. That would include for Bard, the 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 20 Q. Is Align a sling or a prolapse? 21 A. And for Ethicon, it's included 22 Prolift, which is a sling. 3 A. Yes. 4 Q. Can you tell me what those are? 5 A. Yes. For Boston Scientific, that 6 would have included the Uphold, which is a sling. 7 pelvic organ prolapse device, and the 8 Prefix, which is a sling. 9 And for Ethicon, we already addressed Prolift and Prosima. So those are 11 the two pelvic organ prolapse devices. I 12 think the only other sling about which I 13 have given deposition testimony is TVT from 14 Ethicon. 15 Q. Okay. 4 A. And then we've already addressed 16 Bard. 17 Bard. 18 Q. Okay. So no additional products in 19 but it was principally Align. 19 deposition testimony for Bard? 20 A. No. As I mentioned, I had an 21 A. It's a sling. 21 A. Vasulta report which was the focus of the 22 Q. Okay. 23 A. And for Ethicon, it's included 24 Prolift, Prosima, TVT Abbrevo, TVT-O. 24 Prolift, Prosima, TVT Abbrevo, TVT-O.	1		1	testimony in cases involving additional	Page 49
4 Q. Can you tell me what those are? 5 Q. For pelvic mesh? 6 A. Yes. 7 Q. And how many mesh manufacturers has 8 that involved? 9 A. Three. 10 Q. And who are they? 11 A. Ethicon, Boston Scientific, and 12 Bard. 13 Q. All right. 14 A. CR Bard. 15 Q. And which products have you 16 testified at trial for? 17 A. That would include for Bard, the 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 20 Q. Is Align a sling or a prolapse? 21 A. It's a sling. 22 Q. Okay. 24 Prolift, Prosima, TVT Abbrevo, TVT-O. 26 A. Yes. For Boston Scientific, that 4 Q. Can you tell me what those are? 5 A. Yes. For Boston Scientific, that 6 would have included the Uphold, which is a 7 pelvic organ prolapse device, and the 8 Prefix, which is a sling. 9 And for Ethicon, we already addressed Prolift and Prosima. So those are 11 the two pelvic organ prolapse devices. I 12 think the only other sling about which I 13 have given deposition testimony is TVT from 14 Ethicon. 15 Q. Okay. 16 A. And then we've already addressed 17 A. That would include for Bard, the 18 Bard. 19 deposition testimony for Bard? 20 A. No. As I mentioned, I had an 21 A. It's a sling. 21 Avaulta report which was the focus of the 22 Q. Okay. 23 A. And for Ethicon, it's included 24 Prolift, Prosima, TVT Abbrevo, TVT-O. 24 report for Avaulta was also incorporated in		A. I believe it's nine but just let me	I .		Page 49
5 Q. For pelvic mesh? 6 A. Yes. 7 Q. And how many mesh manufacturers has 8 that involved? 9 A. Three. 10 Q. And who are they? 11 A. Ethicon, Boston Scientific, and 12 Bard. 13 Q. All right. 14 A. CR Bard. 15 Q. And which products have you 16 testified at trial for? 17 Q. Is Align a sling or a prolapse? 18 A. That would include for Bard, the 19 but it was principally Align. 20 Q. Is Align a sling. 21 A. And for Ethicon, it's included 22 Prolift, Prosima, TVT Abbrevo, TVT-O. 25 A. Yes. For Boston Scientific, that 26 would have included the Uphold, which is a pelvic organ prolapse device, and the 37 pelvic organ prolapse device, and the 38 Prefix, which is a sling. 39 And for Ethicon, we already 30 addressed Prolift and Prosima. So those are 41 the two pelvic organ prolapse devices. I 42 think the only other sling about which I 43 have given deposition testimony is TVT from 44 Ethicon. 45 Q. Okay. 46 A. And then we've already addressed 47 Bard. 48 Q. Okay. So no additional products in 49 deposition testimony for Bard? 40 A. No. As I mentioned, I had an 41 A. It's a sling. 41 Avaulta report which was the focus of the 42 Q. Okay. 43 A. And for Ethicon, it's included 44 Prolift, Prosima, TVT Abbrevo, TVT-O. 45 A. Yes. 66 would have included the Uphold, which is a pelvic organ prolapse device, and the 47 pelvic organ prolapse device, and the 48 prefix, which is a sling. 4 Prolift, end the Uphold, which is a sling. 4 Prolift, prosima, TVT Abbrevo, TVT-O. 5 A. Yes. 6 would have included the Uphold would held the 4 would have included the Uphold was the 5 pelvic organ prolapse device, and the 5 pelvic organ prolapse device, and the 7 pelvic organ prolapse devices. 7 A. And for Ethicon, we already 8 prolift sat risk included the Uphold was the focus of the 9 pelvic organ prolapse evices. 19 A. And for Ethicon, it's included the Uphold was also incorporated in	2	A. I believe it's nine but just let me check that. Yes, nine.	2	products for pelvic mesh?	Page 49
6 A. Yes. 7 Q. And how many mesh manufacturers has 8 that involved? 9 A. Three. 9 And who are they? 10 Q. And who are they? 11 A. Ethicon, Boston Scientific, and 12 Bard. 13 Q. All right. 14 A. CR Bard. 15 Q. And which products have you 16 testified at trial for? 17 A. That would include for Bard, the 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 20 Q. Is Align a sling or a prolapse? 21 A. And for Ethicon, it's included 22 Prolift, Prosima, TVT Abbrevo, TVT-O. 3 Would have included the Uphold, which is a pelvic organ prolapse device, and the 7 pelvic organ prolapse device, and the 8 Prefix, which is a sling. 7 pelvic organ prolapse device, and the 8 Prefix, which is a sling. 9 And for Ethicon, we already 10 addressed Prolift and Prosima. So those are 11 the two pelvic organ prolapse device, and the 12 think the only other sling about which I 13 have given deposition testimony is TVT from 14 Ethicon. 15 Q. Okay. 16 A. And then we've already addressed 17 Bard. 18 Q. Okay. So no additional products in 19 deposition testimony for Bard? 20 A. No. As I mentioned, I had an 21 A. It's a sling. 21 Avaulta report which was the focus of the 22 Q. Okay. 23 A. And for Ethicon, it's included 24 Prolift, Prosima, TVT Abbrevo, TVT-O. 24 report for Avaulta was also incorporated in	2	A. I believe it's nine but just let me check that. Yes, nine. Q. Okay. Nine trials?	2	products for pelvic mesh?  A. Yes.	Page 49
7 Q. And how many mesh manufacturers has 8 that involved? 9 A. Three. 9 And for Ethicon, we already 10 Q. And who are they? 11 A. Ethicon, Boston Scientific, and 12 Bard. 13 Q. All right. 14 A. CR Bard. 15 Q. And which products have you 16 testified at trial for? 17 A. That would include for Bard, the 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 20 Q. Is Align a sling or a prolapse? 20 Q. Okay. 21 A. And for Ethicon, it's included 22 Prolift, Prosima, TVT Abbrevo, TVT-O. 2 And how many mesh manufacturers has 8 Prefix, which is a sling. 9 And for Ethicon, we already 10 addressed Prolift and Prosima. So those are 11 the two pelvic organ prolapse devices. I 12 think the only other sling about which I 13 have given deposition testimony is TVT from 14 Ethicon. 15 Q. Okay. 16 A. And then we've already addressed 17 Bard. 18 Q. Okay. So no additional products in 19 deposition testimony for Bard? 20 A. No. As I mentioned, I had an 21 Avaulta report which was the focus of the 22 Q. Okay. 23 A. And for Ethicon, it's included 24 Prolift, Prosima, TVT Abbrevo, TVT-O. 25 A. And under self-incomposition was Align, but 26 Prolift, Prosima, TVT Abbrevo, TVT-O. 27 Prolift, Prosima, TVT Abbrevo, TVT-O. 28 Prolift and Prosima. So those are 10 And dressed Prolift and Prosima. So those are 11 the two pelvic organ prolapse devices. I 12 think the only other sling about which I 13 have given deposition testimony is TVT from 14 A. And then we've already addressed 15 Q. Okay. 16 A. And then we've already addressed 17 Bard. 18 Q. Okay. So no additional products in 19 deposition testimony for Bard? 20 A. No. As I mentioned, I had an 21 Avaulta report which was the focus of the 22 Q. Okay. 23 A. And for Ethicon, it's included 24 Prolift, Prosima, TVT Abbrevo, TVT-O. 24 report for Avaulta was also incorporated in	2 3 4	<ul><li>A. I believe it's nine but just let me check that. Yes, nine.</li><li>Q. Okay. Nine trials?</li><li>A. Nine trials.</li></ul>	2 3 4	products for pelvic mesh?  A. Yes. Q. Can you tell me what those are?	Page 49
8 that involved? 9 A. Three. 9 And for Ethicon, we already 10 Q. And who are they? 11 A. Ethicon, Boston Scientific, and 12 Bard. 13 Q. All right. 14 A. CR Bard. 15 Q. And which products have you 16 testified at trial for? 17 A. That would include for Bard, the 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 20 Q. Is Align a sling or a prolapse? 21 Q. Okay. 22 Q. Okay. 23 A. And for Ethicon, it's included 24 Prolift, Prosima, TVT Abbrevo, TVT-O. 20 And who are they? 21 And for Ethicon, we already 24 addressed Prolift and Prosima. So those are 11 the two pelvic organ prolapse devices. I 12 think the only other sling about which I 13 have given deposition testimony is TVT from 14 Ethicon. 15 Q. Okay. 16 A. And then we've already addressed 17 Bard. 18 Q. Okay. So no additional products in 19 deposition testimony for Bard? 20 A. No. As I mentioned, I had an 21 Avaulta report which was the focus of the 22 Q. Okay. 23 A. And for Ethicon, it's included 24 Prolift, Prosima, TVT Abbrevo, TVT-O. 25 Prolift, Prosima, TVT Abbrevo, TVT-O. 26 Profix and Fresing. 27 And for Ethicon, we already 28 And for Ethicon, we already 29 And for Ethicon, we already 29 And for Ethicon, we already 20 A. No. As I mentioned, I had an 21 Avaulta report which was the focus of the 22 Q. Okay. 23 A. And for Ethicon, it's included 24 Prolift, Prosima, TVT Abbrevo, TVT-O.	2 3 4 5	<ul><li>A. I believe it's nine but just let me check that. Yes, nine.</li><li>Q. Okay. Nine trials?</li><li>A. Nine trials.</li><li>Q. For pelvic mesh?</li></ul>	2 3 4 5	products for pelvic mesh?  A. Yes. Q. Can you tell me what those are? A. Yes. For Boston Scientific, that	Page 49
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10 Q. And who are they? 11 A. Ethicon, Boston Scientific, and 12 Bard. 13 Q. All right. 14 A. CR Bard. 15 Q. And which products have you 16 testified at trial for? 17 A. That would include for Bard, the 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 20 Q. Is Align a sling or a prolapse? 21 A. And for Ethicon, it's included 22 Q. Okay. 24 Prolift, Prosima, TVT Abbrevo, TVT-O. 21 think the only other sling about which I 25 think the only other sling about which I 26 think the only other sling about which I 27 think the only other sling about which I 28 think the only other sling about which I 29 think the only other sling about which I 20 Q. Okay. 20 Q. Okay. 21 A. And then we've already addressed 21 A. And then we've already addressed 22 A. And then we've already addressed 23 A. And then we've already addressed 24 A. And then we've already addressed 25 A. And then we've already addressed 26 A. And then we've already addressed 27 A. And then we've already addressed 28 A. And then we've already addressed 29 A. No. As I mentional products in 20 A. No. As I mentioned, I had an 21 Avaulta report which was the focus of the 22 Q. Okay. 23 A. And for Ethicon, it's included 24 report for Avaulta was also discussed, and my 24 report for Avaulta was also incorporated in	2 3 4 5 6 7	<ul> <li>A. I believe it's nine but just let me check that. Yes, nine.</li> <li>Q. Okay. Nine trials?</li> <li>A. Nine trials.</li> <li>Q. For pelvic mesh?</li> <li>A. Yes.</li> <li>Q. And how many mesh manufacturers has</li> </ul>	2 3 4 5 6 7	products for pelvic mesh?  A. Yes. Q. Can you tell me what those are? A. Yes. For Boston Scientific, that would have included the Uphold, which is a pelvic organ prolapse device, and the	Page 49
11 A. Ethicon, Boston Scientific, and 12 Bard. 13 Q. All right. 14 A. CR Bard. 15 Q. And which products have you 16 testified at trial for? 17 A. That would include for Bard, the 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 20 Q. Is Align a sling or a prolapse? 21 A. It's a sling. 22 Q. Okay. 23 A. And for Ethicon, it's included 24 Prolift, Prosima, TVT Abbrevo, TVT-O. 21 think the only other sling about which I 12 think the only other sling about which I 13 have given deposition testimony is TVT from 14 Ethicon. 15 Q. Okay. 16 A. And then we've already addressed 17 Bard. 18 Q. Okay. So no additional products in 19 deposition testimony for Bard? 20 A. No. As I mentioned, I had an 21 Avaulta report which was the focus of the 22 the focus of the deposition was Align, but 23 their Avaulta was also discussed, and my 24 report for Avaulta was also incorporated in	2 3 4 5 6 7 8	<ul> <li>A. I believe it's nine but just let me check that. Yes, nine.</li> <li>Q. Okay. Nine trials?</li> <li>A. Nine trials.</li> <li>Q. For pelvic mesh?</li> <li>A. Yes.</li> <li>Q. And how many mesh manufacturers has that involved?</li> </ul>	2 3 4 5 6 7 8	products for pelvic mesh?  A. Yes. Q. Can you tell me what those are? A. Yes. For Boston Scientific, that would have included the Uphold, which is a pelvic organ prolapse device, and the Prefix, which is a sling.	Page 49
12 think the only other sling about which I 13 Q. All right. 14 A. CR Bard. 15 Q. And which products have you 16 testified at trial for? 17 A. That would include for Bard, the 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 20 Q. Is Align a sling or a prolapse? 21 A. It's a sling. 22 Q. Okay. 23 A. And for Ethicon, it's included 24 Prolift, Prosima, TVT Abbrevo, TVT-O. 25 Is All right. 26 think the only other sling about which I 27 have given deposition testimony is TVT from 28 Have given deposition testimony is TVT from 29 Q. Okay. 20 Okay. 21 A. And then we've already addressed 21 Bard. 22 Q. Okay. So no additional products in 23 deposition testimony for Bard? 24 A. No. As I mentioned, I had an 25 Avaulta report which was the focus of the	2 3 4 5 6 7 8	A. I believe it's nine but just let me check that. Yes, nine. Q. Okay. Nine trials? A. Nine trials. Q. For pelvic mesh? A. Yes. Q. And how many mesh manufacturers has that involved? A. Three.	2 3 4 5 6 7 8 9	products for pelvic mesh?  A. Yes. Q. Can you tell me what those are? A. Yes. For Boston Scientific, that would have included the Uphold, which is a pelvic organ prolapse device, and the Prefix, which is a sling.  And for Ethicon, we already	Page 49
13 Q. All right. 14 A. CR Bard. 15 Q. And which products have you 16 testified at trial for? 17 A. That would include for Bard, the 18 Align. Discussion about Avaulta came up, 19 but it was principally Align. 20 Q. Is Align a sling or a prolapse? 21 A. It's a sling. 22 Q. Okay. 23 A. And for Ethicon, it's included 24 Prolift, Prosima, TVT Abbrevo, TVT-O. 25 Q. And which products have you 16 Ethicon. 17 Q. Okay. 18 Q. Okay. 18 Q. Okay. So no additional products in 19 deposition testimony for Bard? 20 A. No. As I mentioned, I had an 21 Avaulta report which was the focus of the 22 the focus of the deposition was Align, but 23 their Avaulta was also discussed, and my 24 report for Avaulta was also incorporated in	2 3 4 5 6 7 8 9	A. I believe it's nine but just let me check that. Yes, nine. Q. Okay. Nine trials? A. Nine trials. Q. For pelvic mesh? A. Yes. Q. And how many mesh manufacturers has that involved? A. Three. Q. And who are they?	2 3 4 5 6 7 8 9	products for pelvic mesh?  A. Yes. Q. Can you tell me what those are? A. Yes. For Boston Scientific, that would have included the Uphold, which is a pelvic organ prolapse device, and the Prefix, which is a sling. And for Ethicon, we already addressed Prolift and Prosima. So those are	Page 49
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Page 50 Page 52 1 Q. And is Avaulta a sling? 1 A. No. 2 A. No. It's an pelvic organ prolapse 2 Q. Okay. I'm not meaning that to be a 3 3 device. trick question. For instance, like if a 4 4 sling was a predicate for one of these other Q. Okay. I'm just trying to make sure 5 5 I've got all the sling devices where you've products, typically that IFU is within the offered deposition or trial testimony, and 6 6 510(k); right? 7 let me see if I've got them. 7 A. Yes. If you're talking about that, 8 8 A. Okay. yes. In reviewing the 510(k)s. I'm sorry. 9 Q. I have Align, TVT-O, Obtryx, TVT 9 I understood your question to be separately. 10 Abbrevo, Solyx, Prefix, and TVT. 10 Q. Yeah, and I'm not trying to, you 11 A. Yes. 11 know, trick you up on that. But as you sit Q. Okay. And those are from three here today, for instance, in addition to 12 12 different manufacturers? these seven, would you have reviewed the 13 13 ProteGen IFU as it's the predicate for TVT? 14 A. That's correct. 14 A. I don't recall. I would have to 15 Q. All right. Does AMS also make a 15 sling product or they did? look back at the 510(k) to see if the 16 16 ProteGen IFU was included. 17 A. Yes. 17 18 Q. All right. Other than -- have you 18 Q. Okay. I think it was, but as you offered any opinions in any AMS case? sit here today, you don't recall? 19 19 20 A. No, I have not. 20 A. I would have reviewed it if it was, 21 Q. Okay. Is there another mesh 21 yes. 22 manufacturer that makes a sling? 22 Q. Do you recall any other IFUs that might have been within the 510(k)s of these 23 A. There are other manufacturers, yes, 23 seven other products that you might have 24 that make slings. Those --24 Q. Have you reviewed any of those 25 25 reviewed? Page 51 Page 53 manufacturers' documents? A. The predicate -- the predicate 1 1 2 A. No, I have not. 2 devices for those products. 3 Q. All right. 3 Q. Okay. I mean, do you recall what A. Other than in the context of doing 4 4 they were? 5 my report for the products that we've 5 A. Well, certainly, TVT-O's predicates 6 discussed, I do do research and go online 6 were the TVT, the TVT device. 7 and look at 510(k) summaries of safety and 7 O. Yeah. But you reviewed that 8 effectiveness for certain devices. 8 because that's one of your products; right? 9 I've obviously looked at MDR 9 A. Exactly. And then similarly -- let 10 reports, which are included in a number of 10 me just take a moment. So -my reports. So publicly available Q. Can I tell you why I'm asking that? 11 11 information or information that might be in 12 12 A. Sure. Sure. some of the records that have been produced Q. I'm just asking if there's one that 13 13 during discovery for the various cases. stands out to you that you know you reviewed 14 14 15 I may have reviewed information 15 that's not one of these seven sling products about some of the slings or press releases that you and I have already talked about. 16 16 or information that's publicly available. A. No. Many of them, as you know, 17 17 18 but in terms of have I worked on other 18 they all go back -- they go back ultimately manufacturers' sling products in the context to the ProteGen. 19 of reviewing confidential documents to --20 O. Right. 20 21 and arrive at opinions, no, I have not done 21 A. Ultimately in the hierarchy and the 22 that. 22 substantial equivalence decision tree, is Q. Have you reviewed that you can they typically all go back to the ProteGen 23 23 because then TVT relied on the ProteGen for recall any IFUs for slings other than the 24 24 seven that you and I have talked about? 25 its clearance, and then some of these later 25

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	•	Page 54			Page 56
1	devices reference including TVT-O		1	A. The ones that I have reviewed, and	1 1 3 1 1 1
2	references the TVT.		2	I have not for some of these products	
3	And the advantage I would have		3	where I have not done an updated report, if	
4	for example, the Advantage meshes, I would		4	there have been changes since I last opined	
5	have reviewed their for Boston		5	about it, I may not have seen any updates to	
6	Scientific, I would have reviewed their		6	labeling to the IFUs.	
7	IFUs.		7	For those that I have seen, for	
8	Q. Is Advantage a sling?		8	example, the TVT-O, there are improvements,	
9	A. Yes. Advantage and Advantage Fit.		9	and some of the information that I, in fact,	
10	I would have reviewed those.		10	included in my reports going back to even,	
11	Q. All right. And Advantage Fit?		11	if I recall correctly, 2013, information	
12	A. Yes.		12	that I documented then that should have been	1
13	Q. Any others that kind of pop in your		13	included in the IFU has since been included.	
14	mind?		14	Q. Is it adequate?	
15	A. Without checking back, I can't		15	A. No. And as I stated in my	
16	recall for sure. I may have I may have		16	supplemental report, which we've marked as	
17	looked at Monarc or		17	Exhibit 6, there are still there is still	
18	Q. SPARC?		18	missing information as regards safety and	
19	A. Pardon me?		19	risk even in the updated 2015 IFU for TVT-O.	
20	Q. SPARC?		20	Q. Okay. So to get a clean question	
21	A. SPARC possibly. MiniArc. Without		21	and answer, if I could, is there any IFU	
				·	
22	checking back, I can't confirm, but I may		22	that you've reviewed, even up to the present	
23	have looked at those.		23	day, that you consider adequate?	
24	Q. Okay. All right. And so now as we		24	A. No.	
25	sit here today, we've got one, two, three,		25	Q. Okay. And I don't know if I I	
	form the six serves sight wine discus-	Page 55		was talking about alian IEUs. Van haan	Page 57
1	four, five, six, seven, eight, nine slings	Page 55	1	was talking about sling IFUs. You knew	Page 57
2	where you think you've reviewed the IFU for	Page 55	2	that; right?	Page 57
2	where you think you've reviewed the IFU for those slings?	Page 55	2	that; right? A. Yes. Yes.	Page 57
2 3 4	where you think you've reviewed the IFU for those slings?  A. Yes.	Page 55	2 3 4	that; right? A. Yes. Yes. Q. All right. What is your hourly	Page 57
2 3 4 5	where you think you've reviewed the IFU for those slings?  A. Yes.  Q. All right. Now, out of those nine,	Page 55	2 3 4 5	that; right? A. Yes. Yes. Q. All right. What is your hourly rate for work?	Page 57
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	where you think you've reviewed the IFU for those slings?  A. Yes.  Q. All right. Now, out of those nine, did you ever determine that the IFU was adequate?  A. No. I found them all to be inadequate.  Q. All right. Is there any IFU for a sling product today that you believe is adequate?  A. There are some that are improved over what they were, but they're still for example, in the  Q. Can I get a yes or no to the question first? Are there any IFUs for a sling product today that you believe are adequate?  A. Well, as we already mentioned, I have not reviewed all sling IFUs.  Q. The ones you have.  A. So I can only speak to the ones	Page 55	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	that; right? A. Yes. Yes. Q. All right. What is your hourly rate for work? A. \$500 an hour. Q. Is that for deposition and review of documents? A. Yes. Q. All right. Are you charging 500 an hour today? A. Yes. Q. Do you have a if you're here all day, do you have an amount that you charge for the entire day that's different than your hourly rate? A. No. Q. Did you meet with plaintiff counsel before today in order to prepare for your deposition? A. Yes. Q. All right. What did you do when you met with him?	Page 57

					i
		Page 58			Page 60
1	BY MS. SUTHERLAND:		1	BY MS. SUTHERLAND:	
2	Q. What did you review?		2	Q. How many times did you meet with	
3	MR. GOSS: What did you review?		3	counsel to prepare for your deposition	
4	Okay.		4	today?	
5	THE WITNESS: We talked about		5	A. Just once.	
6	GHTF.		6	Q. And when was that?	
7	MR. GOSS: Wait a minute.		7	<u>=</u>	
				A. Yesterday afternoon.	
8	THE WITNESS: Oh, sorry.		8	Q. And how long did you all meet?	
9	BY MS. SUTHERLAND:		9	A. Two-and-a-half to three hours.	
10	Q. Keep going, though.		10	Q. And where did you meet?	
11	No, what documents did you review?		11	A. Here.	
12	MR. GOSS: Listen, I'm going to		12	Q. How much time have you put into the	
13	instruct you not to answer that		13	Jennifer Ramirez case?	
14	question. There's an agreement, as I		14	<ul> <li>A. In anticipation of your asking me</li> </ul>	
15	understand it, that we're not getting		15	that, I attempted to evaluate that last	
16	into each other's discussions with		16	night. As you know, there's a lot of	
17	experts beforehand and what we showed		17	crossover between the reports and what's	
18	experts beforehand. That's my		18	relevant to her case as well. Specific to	
19	understanding. If you want to		19	her case and, as you know, also this case	
20	MS. SUTHERLAND: I'll check at		20	has been continued a couple of times and, in	
21	a break because I don't know.		21	fact, preparing for deposition on another	
22	MR. GOSS: At a break, maybe if		22	occasion and it ended up being canceled	
23	you want to check but		23	towards the time that it was supposed to	
24	•		24	·	
25	MS. SUTHERLAND: Right now		25	occur, if I'm recalling correctly as I sit	
25	you're instructing her?		25	here today.	
		Page 59			Page 61
1	MR. GOSS: Right now I'm	ruge 33	1	So I went back and looked at that	ruge or
2	instructing her not to answer because I		2	time, and to the best I'm able to estimate	
3	certainly know there's agreements about,		3	it at this point in time, it was	
4	you know, drafts reports and things like		4	approximately 107 hours specific for this	
5	that.		5	case.	
6	MS. SUTHERLAND: I'm not asking		6	Q. Okay. Now, would that include, for	
7	about draft reports. I was asking her		7	instance, time spent on your supplemental	
8	what she looked at to prepare for her		8	TVT-O report from March, 2016?	
9	deposition today, and if you're		9	A. No.	
10	instructing her not to answer that		10	Q. All right. So that would be	
11	MR. GOSS: I'm instructing her		11	since this is now part of your opinions in	
12	not to answer. I object to foundation		12	this case, would that be additional time?	
13	and		13	A. Yes.	
14	MC CUTUEDIAND. Har III		14	Q. Do you know how much that would be?	· I
	MS. SUTHERLAND: then I'll				I
15	ensure that we're on the same page.		15	A. I think at the last deposition that	
16	ensure that we're on the same page.  MR. GOSS: I'm instructing		15 16	A. I think at the last deposition that I included the preparation for this in	
16 17	ensure that we're on the same page.  MR. GOSS: I'm instructing her not to answer.		15 16 17	A. I think at the last deposition that I included the preparation for this in the in a total of time that I gave you	
16	ensure that we're on the same page.  MR. GOSS: I'm instructing		15 16	A. I think at the last deposition that I included the preparation for this in	
16 17	ensure that we're on the same page.  MR. GOSS: I'm instructing her not to answer.		15 16 17	A. I think at the last deposition that I included the preparation for this in the in a total of time that I gave you	
16 17 18	ensure that we're on the same page.  MR. GOSS: I'm instructing her not to answer.  BY MS. SUTHERLAND:		15 16 17 18	A. I think at the last deposition that I included the preparation for this in the in a total of time that I gave you because I put two supplemental reports	
16 17 18 19	ensure that we're on the same page.  MR. GOSS: I'm instructing her not to answer.  BY MS. SUTHERLAND:  Q. Well, did you review any documents		15 16 17 18 19	A. I think at the last deposition that I included the preparation for this in the in a total of time that I gave you because I put two supplemental reports together in close proximity, and I didn't	
16 17 18 19 20 21	ensure that we're on the same page.  MR. GOSS: I'm instructing her not to answer.  BY MS. SUTHERLAND: Q. Well, did you review any documents to prepare for your deposition today?  MR. GOSS: Same objection.		15 16 17 18 19 20 21	A. I think at the last deposition that I included the preparation for this in the in a total of time that I gave you because I put two supplemental reports together in close proximity, and I didn't separate out how much time for this report specifically. I haven't billed for that	
16 17 18 19 20 21 22	ensure that we're on the same page.  MR. GOSS: I'm instructing her not to answer.  BY MS. SUTHERLAND: Q. Well, did you review any documents to prepare for your deposition today?  MR. GOSS: Same objection. MS. SUTHERLAND: Are you		15 16 17 18 19 20 21 22	A. I think at the last deposition that I included the preparation for this in the in a total of time that I gave you because I put two supplemental reports together in close proximity, and I didn't separate out how much time for this report specifically. I haven't billed for that yet; so I can't give you a specific answer.	
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16 17 18 19 20 21 22	ensure that we're on the same page.  MR. GOSS: I'm instructing her not to answer.  BY MS. SUTHERLAND: Q. Well, did you review any documents to prepare for your deposition today?  MR. GOSS: Same objection. MS. SUTHERLAND: Are you		15 16 17 18 19 20 21 22	A. I think at the last deposition that I included the preparation for this in the in a total of time that I gave you because I put two supplemental reports together in close proximity, and I didn't separate out how much time for this report specifically. I haven't billed for that yet; so I can't give you a specific answer.	

		Page 62			Page 64
1	Q. Are you hoarding them up to give	- 50 02	1	actually totalling it.	- 30 0 1
2	them one painful invoice at the end?		2	Q. Do you know if it's more than	
3	A. I often I often wait until a		3	a million?	
4	case is finished or a project is finished		4	MR. GOSS: Objection. Form.	
5	and bill at the end. That's one way that I		5	THE WITNESS: Not without going	
6	frequently bill.		6	back and tallying it. I don't think	
7	Q. And you keep up with your hours		7	it's more than a million, but I wouldn't	
8	how? Since this case has been going on for		8	want to rely on that with great fact in	
9	so long, how do you keep up with your hours		9	doing my calculations.	
10	on it?		10	BY MS. SUTHERLAND:	
11	A. They get recorded ultimately,		11	Q. Okay. Do you have that information	
12	they get recorded from I document my		12	available in your QuickBooks?	
13	hours, and then they get put into		13	A. Yes.	
14	QuickBooks.		14		
	-			Q. All right. And so that's would	
15	Q. Okay. And have other people at		15	it be an undue burden to find that out for	
16	Symbion billed on the Jennifer Ramirez case?		16	me?	
17	A. Yes.		17	A. Sure. I can find that out.	
18	Q. And are you including their time in		18	Q. Mean it would not be an undue	
19	your time when you tell me about 107 hours?		19	burden?	
20	A. No. That's my time.		20	A. No. I'm sorry.	
21	Q. All right. Do you know how much		21	Q. No worries.	
22	time first of all, let me ask you this:		22	And when I talk about the pelvic	
23	How many other people have worked on the		23	mesh litigation against Ethicon and J&J, you	
24	Jennifer Ramirez case for you?		24	know I'm talking about both your work on the	
25	A. Again, because this has been		25	prolapse products as well as the sling	
		Page 63			Page 65
1	ongoing for probably a couple of years, if I	Page 63	1	products?	Page 65
1 2	ongoing for probably a couple of years, if I recall correctly. I would need to go back	Page 63	1 2	products? A. Yes. Yes.	Page 65
2	recall correctly, I would need to go back	Page 63	2	A. Yes. Yes.	Page 65
2	recall correctly, I would need to go back and just double-check, but I would	Page 63	2 3	A. Yes. Yes. Q. Okay. Do you know how many	
2 3 4	recall correctly, I would need to go back and just double-check, but I would anticipate that or I would believe that at	Page 63	2 3 4	A. Yes. Yes. Q. Okay. Do you know how many documents you've reviewed in the pelvic mesh	
2 3 4 5	recall correctly, I would need to go back and just double-check, but I would anticipate that or I would believe that at least at least three to four other people	Page 63	2 3 4 5	A. Yes. Yes. Q. Okay. Do you know how many documents you've reviewed in the pelvic mesh litigation for Ethicon and J&J?	
2 3 4 5 6	recall correctly, I would need to go back and just double-check, but I would anticipate that or I would believe that at least at least three to four other people have worked on this case at one point in	Page 63	2 3 4 5 6	A. Yes. Yes. Q. Okay. Do you know how many documents you've reviewed in the pelvic mesh litigation for Ethicon and J&J? A. Thousands.	
2 3 4 5 6 7	recall correctly, I would need to go back and just double-check, but I would anticipate that or I would believe that at least at least three to four other people have worked on this case at one point in time or another.	Page 63	2 3 4 5 6 7	A. Yes. Yes. Q. Okay. Do you know how many documents you've reviewed in the pelvic mesh litigation for Ethicon and J&J? A. Thousands. Q. Okay. Do you know how many	
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Page 66 Page 68 been around 5 percent or less in 2008, and 1 percentage. I know -- you can see from 1 2 the volume the size of the -- I'll just 2 then over the period of time, it moved to 3 maybe 20 percent. And because, as we were reiterate what I said a few moments ago, 3 4 you can see from the volume of the 4 discussing earlier, the mesh litigation is 5 5 so large, and there's been -- it's at a reliance list the numbers of documents 6 that have been reviewed. 6 point in time when there are so many cases 7 BY MS. SUTHERLAND: 7 going to trial and so much happening in the 8 8 O. Do you think it's been a million litigation that my time involved in 9 9 litigation work has certainly increased over pages? 10 A. It may be. I just don't have a 10 the last -- over the last couple of years. 11 number to give you. I can only say it's 11 I think my testimony -- I may have been a very large volume of documents, and I said maybe greater than 50 percent, and it 12 12 have cabinets full of binders as well as depends really on the -- what's going on, 13 13 what I have archived electronically. what's happening at any particular time. 14 14 I have multiple cabinets full of Sometimes it's higher than that. Sometimes 15 15 binders of TVT and TVT-O and Prolift and it may be less than that. 16 16 Prosima and TVT Abbrevo. I'm teaching, and I'm getting ready 17 17 18 Q. And those multiple binders you're 18 to start class again. When I'm teaching, talking about would be on the exhibit lists, that takes up a large part of my time, and I 19 19 the reliance lists that we've marked today? 20 20 work on other projects as well. So it A. Yes. Yes. Because I'm still old 21 really depends on what's happening. 21 school enough that I like to use hard copy Sometimes it -- in certain weeks, 22 22 as well as electronic copies. 23 23 it may be all encompassing. Almost. Not 24 Q. Do you know that you have not 24 entirely. But in other weeks, I'll be 25 reviewed all of the documents produced by 25 focused on teaching and not do anything on Page 67 Page 69 Ethicon and J&J in this litigation? 1 the litigation side. 1 2 2 MR. GOSS: Objection. Form. O. Do you think it was over 50 percent THE WITNESS: It's my 3 3 last vear? A. Yes. I think that's fair. understanding that I wouldn't have 4 4 5 reviewed all of the documents that have 5 Q. All right. So far this year, has 6 been produced. 6 it been over 50 percent? 7 BY MS. SUTHERLAND: 7 A. So far this year, yes. 8 8 Q. Okay. Do you know by how much over Q. Okay. 9 A. But the ones that are relevant to 9 50 percent? 10 my opinions, I have reviewed. 10 A. No. I haven't done a calculation. Q. Do you know what percentage of your Q. And has your work been for 11 11 income has come from expert consulting work 12 12 plaintiffs? in the past five years? 13 13 A. Yes. A. I haven't averaged it over the last Q. Consistently since you started 14 14 15 five years. I have provided testimony on 15 consulting in 2008? that before in previous -- in previous A. No. 16 16 depositions and at trial, if I recall Q. All right. When did it become 17 17 18 correctly. Certainly in depositions. 18 consistent for plaintiffs? A. Without checking back the dates, I When I first began product 19 19 20 liability litigation work, I was first 20 can't give you an exact date. The point is contacted the latter part of 2008 and really I evaluate each case. If what you're asking 21 21 began doing work in 2009 to any great is do I only work for plaintiffs, I evaluate 22 22 extent. And it's progressed from -- to the each case, and I take -- I don't take every 23 23 best of my recollection as I sit here today, 24 24 case that I'm asked about. 25 I think what I've indicated is it may have 25 So I evaluate to see if whether or

Page 70 Page 72 not the opinions that I would be -- are the 1 case that you've been asked to opine about 2 allegations that are being made based on 2 you, in fact, have opined about. Is that what I can review are something that I 3 3 fair? 4 believe that I could support, that my 4 A. After reviewing the information and 5 5 opinions based on what I review would be seeing whether or not my opinions would be consistent with what counsel -- counsel's 6 consistent with the claims that -- yes. 6 7 claims are. 7 Q. Okay. So the answer to my question 8 8 is yes? Every pelvic mesh case you've been If they're not, I don't take the asked about, to opine about you have, in 9 case. I don't --10 Q. In the -- I'm sorry. Were you 10 fact, opined about? Is that fair to give me 11 done? 11 a yes or no? 12 A. I was just going to say I'm very --12 A. To the best of my recollection as I I will not testify or take any case if my 13 13 sit here today, yes. opinions are not 100 percent consistent with 14 14 Q. Okay. the claims that are being made. 15 15 MS. SUTHERLAND: Let's, yeah, If I review those, and I think that 16 16 let's take a break. there's an issue, I don't take the case. I 17 17 THE VIDEOGRAPHER: With the 18 have to believe and stand behind my 18 approval of counsel, going off the opinions. 19 record. The time is approximately 19 20 20 Q. Okay. In the past five years, have 10:53 a.m. you taken a case for a defendant? 21 (Recess taken from 21 22 A. Yes. 22 10:53 a.m. to 11:01 a.m.) 23 Q. Okay. Who was that? 23 THE VIDEOGRAPHER: With the 24 A. It was for -- it was a pain -- it 24 approval of counsel, back on the record. was a pain pump case, and it was --25 25 The time is approximately 11:01 a.m. Page 71 Page 73 1 MR. GOSS: Can we take a 1 BY MS. SUTHERLAND: 2 bathroom break after this line of 2 O. Dr. Pence, sooner or later, we're 3 3 going to get into your opinions in this questioning? 4 MS. SUTHERLAND: Yeah, yeah. 4 case. 5 Time flies. 5 Have you published any of your 6 6 opinions that you're intending to offer in MR. GOSS: Too many Diet Cokes 7 7 this case? this morning. 8 8 THE WITNESS: It was a A. No. 9 contractual issue between one pain pump 9 Q. Have you ever spoken with any 10 manufacturer and DJO. 10 scientist about the opinions you intend to BY MS. SUTHERLAND: offer in this case? 11 11 Q. Okay. Let me change my question. A. If you can clarify your question, I 12 12 13 A. Okay. 13 am a scientist; so I'm not sure what the 14 Q. Because I'm really just interested 14 question is. 15 in product liability cases where a plaintiff 15 Q. Well, other than talking to is alleging they got hurt. yourself, have you talked with any other 16 16 scientist about your opinions in this case? Have you worked for a defendant in 17 17 18 a product liability case in the past five 18 A. I've not talked with any other scientists. I've certainly read deposition 19 years? 19 20 A. No. testimony. I've read expert reports. I've 20 read internal documents of Ethicon's own 21 Q. All right. Have you turned down a 21 22 pelvic mesh case that you were asked to 22 scientist. Q. Have you talked -- and I'm talking 23 review? 23 about talked. I understand what you've read 24 A. Not a pelvic mesh case, no. 24 25 Q. All right. So every pelvic mesh 25 and what's on your reliance list. Have you

Page 74 Page 76 talked with any engineers about your O. Yeah. 1 1 2 opinions in this case? 2 A. But I didn't talk with them about 3 3 A. No, I have not. what should be in an IFU specifically, no. 4 4 Q. All right. And then other than Q. Okay. Let me ask it cleanly. 5 5 physicians that are paid by plaintiffs to be Have you talked with any physicians 6 expert witnesses, have you talked with any 6 about the opinions you have expressed in the 7 physicians about your opinions that you're 7 pelvic mesh litigation about IFUs? 8 intending to give in this case? 8 A. As I understand your question, no. 9 MR. GOSS: Objection. Form. 9 Q. Okay. All right. Is it fair to 10 THE WITNESS: I haven't talked 10 say that the opinions that you're going to 11 with physicians about my opinions in 11 opine about in the Jennifer Ramirez case you developed specifically for litigation? 12 this case, including those, as you 12 noted, that are paid by plaintiffs for A. Let me answer that this way: I was 13 13 this particular case. My opinions are asked to review the relevant documentation 14 14 based on my review of the deposition -and deposition testimony related to the 15 15 clearance and marketing of the TVT-O and a number of depositions of both Ethicon 16 16 17 employees as well as the depositions whether or not Ethicon met the standard of 17 18 that are referenced in the reliance list 18 care for not only preparation of the IFU but that we went through earlier, internal for testing, its responsibilities for 19 19 20 documents, standards, and an integration 20 post-market surveillance, and so forth. As a part of being a regulatory 21 of all that information and analysis to 21 22 affairs professional, if you look at -- and 22 arrive at my opinions. BY MS. SUTHERLAND: I'm a RAPS fellow, and the reason I bring 23 23 24 Q. Right. My -- with all due respect, 24 that up is because there is a level of I'm going to move to strike. 25 25 experience in order to achieve that level Page 75 Page 77 But my question is: Just did you 1 that one must meet, and a part of that is 1 2 talk with any physicians about your opinions 2 being able to evaluate package inserts, 3 in this case? 3 instructions for use, labeling, and know 4 4 A. No. what goes in labeling. That's part of my 5 5 Q. And, obviously, you've offered credentials. opinions on the adequacy of IFUs in pelvic 6 So I evaluated all of the 6 7 mesh cases, including this one; correct? 7 information that I -- as I mentioned, 8 A. Yes, that is correct. 8 deposition testimony, internal documents, 9 Q. All right. Now, as I understand 9 what the company knew or didn't know, it, you have talked with plaintiff expert 10 scientific and medical -- what the company 10 physicians about pelvic mesh IFUs; is that knew or didn't know based on their own 11 11 right? 12 12 internal documents, or what they should have known, scientific literature, the publicly 13 A. Can you clarify your question? 13 Q. Yeah. I thought you had testified available MAUDE database, not only for its 14 14 15 in one case earlier that you had talked with 15 own products but for other products where Dr. Rosenzweig about an IFU in a pelvic mesh complications and other safety issues have 16 16 17 case. 17 been reported. 18 Do you recall talking to him about 18 I evaluated all of that in the context of FDA regulations as well as global 19 an IFU? 19 20 A. No. I think, to the best of my industry standards and my experience and 20 knowledge, based on the level 4 experience 21 recollection as I sit here today, what you 21 22 may be referring to is I was asked whether I 22 that I have as a regulatory affairs had spoken to any physicians about pelvic professional and product development 23 23

scientist in the medical device world, and

that's how I arrived at my opinions as

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mesh issues, and I would have mentioned

Dr. Rosenzweig and Dr. Margolis.

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Page 78 Page 80 regards what should have been in the followed is the very same methodology 1 1 2 labeling and was missing from the labeling. 2 and process that I follow for a Q. Okay. And I'm not quite sure you 3 3 pharmaceutical or medical device client 4 answered my question. Let me ask it this 4 where I'm assisting them with labeling. 5 5 way: The items that you just told me about BY MS. SUTHERLAND: that you reviewed, you did that because 6 Q. And I got that. My question is: 6 7 plaintiff's lawyers asked you to? 7 Didn't that process start, in fairness, 8 A. They asked me to review the 8 Dr. Pence, because plaintiff lawyers asked 9 documentation and arrive at opinions. 9 vou to? Q. Right. 10 10 MR. GOSS: Objection to form. 11 A. I told them the kinds of 11 BY MS. SUTHERLAND: 12 information that I needed to review, and I 12 Q. Isn't that true? 13 did some of my own independent research as 13 A. For the mesh products, that is true. That was -- that was what I was asked 14 well. 14 to review the information, let them know 15 Q. Okay. 15 A. And then, of course, I know the what my opinions would be. 16 16 standards that are applicable. O. FDA didn't ask you for your 17 17 18 Q. Right. 18 opinions on pelvic mesh; correct? A. No, they did not. 19 A. And it was based on that that I 19 20 arrived at my opinions, but I was asked to 20 Q. And no mesh manufacturer asked you for your opinions on pelvic mesh; right? let counsel know what my opinions would be. 21 21 Q. And that whole process of this A. No, they have not. 22 22 review of pelvic mesh documents, et cetera, Q. All right. So the folks that have 23 23 24 began because plaintiff lawyers asked you 24 asked you for your opinions on pelvic mesh for your opinions; correct? have been plaintiff lawyers? 25 25 Page 79 Page 81 A. Yes. Just as it would be the --1 A. Yes. That said, the 2015 update to 1 2 2 but it would be the same type of the labeling for TVT and TVT-O reflects much 3 methodology, the same type of process. 3 of what I -- a number of the -- a lot of the 4 Q. I'm just asking how the process got safety information that I stated in my 4 5 started --5 report was missing and should have been 6 MR. GOSS: Please let her 6 included, and that now has been included. 7 7 MS. SUTHERLAND: Okay. I'm finish her answer. 8 8 THE WITNESS: In a consulting going to move to strike everything after 9 agreement with the client where I would 9 "ves." 10 be helping them with developing their 10 BY MS. SUTHERLAND: 11 labeling, I would undertake the same Q. Are you intending to offer any 11 type of evaluation and say, "No, this is specific causation opinion in the Jennifer 12 12 what we need to put in the labeling for Ramirez case? 13 13 it to meet the standard of care for the 14 14 A. No. 15 purpose of medical device labeling." 15 Q. All right. Are you intending to BY MS. SUTHERLAND: offer any general causation opinion in the 16 16 Jennifer Ramirez case? Q. Okay. I think I'm going to move to 17 17 18 strike everything after "yes" because my 18 A. No. question really was you started this process 19 19 Q. All right. Are you intending to because plaintiff lawyers asked you to. 20 offer an opinion on manufacturing defect in 20 21 Isn't that fair? 21 the Jennifer Ramirez case? MR. GOSS: I'm sorry. Can you 22 MR. GOSS: Objection, Form. 22 THE WITNESS: It's a fair 23 23 repeat that? 24 question, but I think it needs to be 24 THE WITNESS: Do you want me to 25 characterized that the process that I 25 rephrase it?

	•	Page 82			Page 84
1	MR. GOSS: Yes.	3	1	Q. So, again, just getting back	J
2	BY MS. SUTHERLAND:		2	specific to Mrs. Ramirez's batch	
3	Q. Are you intending to offer a		3	A. Yes.	
4	manufacturing defect opinion in the Jennifer		4	Q is what you're going to offer	
5	Ramirez case?		5	that there were reports or devices returned	
			6	from her same batch?	
6	MR. GOSS: Objection. Form.		_		
7	THE WITNESS: If you are asking		7	A. There were at least two complaints	
8	about and I recall a similar question		8	about the batch from which her sling was	
9	a couple of weeks ago, I believe. If		9	made of fraying particle loss.	
10	you're asking about the manufacturing		10	Q. Okay. Did Dr who is the	
11	process itself, maybe you can clarify,		11	implanter in this case?	
12	or are you asking about whether or not		12	A. Cesar Reyes. Dr. Cesar Reyes.	
13	the product degrades, whether or not		13	Q. Okay. Did Dr. Reyes in his	
14	BY MS. SUTHERLAND:		14	deposition did he mention anything about	
15	Q. Yeah. It's the same thing I did		15	noticing any fraying of the TVT-O before he	
16	two weeks ago. I'm not asking you about		16	implanted it?	
17	defects like degradation, roping, curling,		17	A. To the best of my recollection, he	
18	et cetera, that other plaintiffs' experts		18	did.	
19	have opined about.		19	MR. GOSS: I'm sorry. Can you	
20	My question to you is for the lot		20	repeat that?	
21	or batch that Mrs. Ramirez, this TVT-O came		21	MS. SUTHERLAND: Was that an	
22	out of, do you have any opinions that you		22	objection?	
23	intend to offer about the manufacturing		23	MS. VERBEEK: Yes.	
24	processes for that batch?		24	THE REPORTER: Can you repeat	
25	A. I intend to offer opinions, if		25	the objection?	
	7 ii 1 iiicciia to oiici opiiioio, ii			are objections	
		Page 83			Page 85
1	asked about the fact that that lot that	Page 83	1	MS_VERBEEK: I objected to the	Page 85
1 2	asked, about the fact that that lot, that	Page 83	1 2	MS. VERBEEK: I objected to the	Page 85
2	there had been complaints about that lot for	Page 83	2	form of the question.	Page 85
2	there had been complaints about that lot for mesh fraying.	Page 83	2	form of the question.  THE REPORTER: Thank you.	Page 85
2 3 4	there had been complaints about that lot for mesh fraying. Q. And what opinions, if asked, are	Page 83	2 3 4	form of the question.  THE REPORTER: Thank you.  MR. GOSS: I don't recall. Do	Page 85
2 3 4 5	there had been complaints about that lot for mesh fraying.  Q. And what opinions, if asked, are you going to give on that particular topic?	Page 83	2 3 4 5	form of the question.  THE REPORTER: Thank you.  MR. GOSS: I don't recall. Do  we have an agreement that an objection	Page 85
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Page 86 Page 88 Q. Okay. I'm trying to think how to 1 1 batch, that already there were other phrase this one. Are you intending to offer 2 2 complaints. an opinion that because there were reports 3 3 So if asked, I will testify that 4 received within her same batch, that 4 that certainly was a -- you know, could have 5 Mrs. Ramirez's TVT-O must have fraved as 5 happened. And not only that, but there's 6 much documentation that says this was in -well? 6 7 A. The potential was there. It's 7 the fraying and the particle loss was 8 8 inherent in the mesh, the mechanically cut in -- the potential was there for fraying, roping, curling, and a degradation of the 9 mesh, which was the whole impetus for the 10 mesh structure with any type of stretching. 10 development of the laser-cut mesh. So it's 11 Q. Okay. I'm talking specifically, 11 inherent, by Ethicon's own words, in the though, because I think your report mechanically cut mesh, and then for her 12 12 mentioned those two other reports from the particular batch, for there to have been 13 13 other complaints, there certainly was a 14 batch. 14 potential that on implantation, even if 15 A. Yes. 15 Dr. Reyes didn't notice fraying at the time 16 Q. And my question is -- I understand 16 all that, that the opinions on degradation, he took it out to implant it, that it could 17 17 18 roping, curling, fraying that are generic to 18 have frayed, and there could have been TVT and the Prolene. My question is a particle loss, and as I mentioned, there 19 19 20 little more specific as to Mrs. Ramirez and 20 have been complaints of particle loss -- the her specific batch, and my question is: Are 21 particles that are lost migrating into the 21 you intending to offer an opinion that 22 22 vaginal wall causing pain and causing pain because of these two other reports from the 23 23 on -- dyspareunia. batch about fraying, that her, 24 Q. Let me try it this way: Are you 24 25 Mrs. Ramirez's TVT-O must also have frayed 25 going to say that Mrs. Ramirez's tape was Page 87 Page 89 based on those two reports? 1 frayed because of these other two reports? 1 2 2 A. A couple of points to be made. We A. I can't say it was frayed because I 3 know that there were other slings in that 3 wasn't there. batch, as you've just described, that did 4 4 Q. Okay. 5 fray, although Dr. Reyes testified that he 5 A. But what I can say is the company 6 didn't see that. He was not aware, based on knew that this was a defect in the product. 6 7 7 The company knew that this happened often, his testimony, that there was also a 8 8 and for this particular batch, they had laser-cut mesh. 9 Ethicon did not -- never did tell 9 specific complaints that showed it was an 10 doctors that had noticed this fraying about 10 issue with other slings from this batch. So the issues with fraying and roping and there was certainly a potential for fraying 11 11 12 curling. So whether or not Dr. Reyes 12 when it was implanted. actually looked for that, only Dr. Reyes can 13 13 O. Okay. I'm going to move to strike know. And as I sit here today to the best everything after "I can't say it was 14 14 15 of my recollection, I don't believe there 15 fraved." was a lot more discussion about whether or Let me ask you -- changing gears. 16 16 Let me ask you this: Obviously, you've got not he saw any particle loss or fraying 17 17 18 other than that. 18 a number of opinions in this case. 19 Whether or not he actually looked 19 A. Yes. 20 in the packaging to see if there were any 20 Q. Have you conducted any studies to support your opinions in this case? particles, I don't know. I only know what 21 21 he testified to. My point being that also 22 22 MR. GOSS: Objection, Form. on stretching, just the stretching that THE WITNESS: Can you clarify 23 23 occurs with implanting it, it could have 24 24 what you mean? frayed. We know it was, in that particular 25 BY MS. SUTHERLAND: 25

Page 90  1 Q. Sure. Other than reviewing 2 documents and obviously applying your 3 expertise and your experience, have you 4 otherwise conducted any studies to  Page 90  1 information, and Ethi 2 manufacturer, has a significant of the photography. 3 provide that manufacturer, has a significant of the photography.	Page 92
2 documents and obviously applying your 2 manufacturer, has a constraint of the photon	
2 documents and obviously applying your 2 manufacturer, has a constraint of the photon	con, as the
3 expertise and your experience, have you 4 otherwise conducted any studies to 3 provide that manufact 4 information to the ph	,
4 otherwise conducted any studies to 4 information to the ph	
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5 substantiate any of your opinions in this 5 the patient in the cor	•
6 case? 6 brochures, if they're	·
1 ' ' '	
	octor can only relay to
8 THE WITNESS: If you're asking 8 the patient what the	
9 if I've conducted animal studies or 9 And if Ethicon d	
	nsibility to provide the
11 BY MS. SUTHERLAND: 11 information to the do	
12 Q. Have you conducted any surveys of 12 or she understands a	ll the risks, then, as
13 physicians to substantiate any of your 13 stated in my report, t	then the consenting
14 opinions? 14 process is negatively	affected because a
15 MR. GOSS: Objection. Form. 15 true, full informed co	nsent can't be done
16 THE WITNESS: Specific to this 16 because all the risks	aren't known.
	RLAND: I'm going to
1	erything after "no, I
19 Q. All right. Have you conducted any 19 have not."	,
20 surveys of women at all I'll leave it 20 BY MS. SUTHERLAND	):
· · · · · · · · · · · · · · · · · · ·	question really was
22 surveys of women to substantiate your 22 only to you whether	
23 opinions in this case? 23 performed any kind of	•
1 '	
, , , , , , , , , , , , , , , , , , , ,	s perceptions of the TVT-O
25 Q. I'll give you an example. For 25 patient brochure are.	
Page 91	Page 93
1 instance and we'll get into it. One of 1 A. No. As you've	
	asked the duestion.
	asked the question,
2 your opinions, as I understand it, is that 2 no.	·
2 your opinions, as I understand it, is that 2 no. 3 the patient brochure is misleading. 3 Q. Okay. That was	asn't so hard, was it?
<ul> <li>2 your opinions, as I understand it, is that</li> <li>3 the patient brochure is misleading.</li> <li>4 For example, have you conducted a</li> <li>2 no.</li> <li>3 Q. Okay. That was a part of the patient brochure is misleading.</li> <li>4 Have you ever the patient brochure is misleading.</li> <li>5 Have you ever the patient brochure.</li> </ul>	asn't so hard, was it? worked at FDA?
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	Page 9			Page 96
1	A. No.	1	involvement in litigation on pelvic mesh,	
2	Q. Has the FDA ever asked for your	2	had you had any involvement whatsoever with	, İ
3	opinion about instructions for use for	3	any pelvic mesh device?	'
	·			
4	pelvic mesh products?	4	A. In women's health issues, yes, but	
5	A. No.	5	not a pelvic mesh device specifically, no.	
6	Q. Has FDA ever asked for your opinion	6	Q. Okay. And the woman's health	
7	about patient brochures of pelvic mesh	7	device that you're talking about, what was	
8	products?	8	that?	
9	A. No.	9	<ul> <li>A. It's women's health, a variety of</li> </ul>	
10	<ul><li>Q. Has FDA ever asked for your opinion</li></ul>	10	health issues, both drugs and medical	
11	about anything regarding pelvic mesh?	11	devices. And, again, I'm unable to disclose	
12	A. No.	12	what products specifically because of my	
13	Q. Were you invited to be part of the	13	confidentiality agreements with the clients.	
14	2011 AdCom concerning pelvic mesh?	14	Q. So would it be correct to say that	
15	A. No.	15	prior to your involvement in litigation, you	
16	Q. Have you ever spoken to anybody at	16	had not had any involvement whatsoever in	
17	the FDA concerning your opinions regarding	17	pelvic mesh devices?	
18	pre-market testing of pelvic mesh products?	18	A. That's fair to say, yes.	
19	A. No.	19	Q. Okay. Are you intending to offer	
20	Q. And have you ever spoken to any	20	any criticisms of FDA as part of your	
	manufacturer outside the context of		opinions at trial?	
21		21	•	
22	litigation about pre-market testing for	22	A. No.	
23	pelvic mesh products?	23	Q. Outside of litigation, have you	
24	A. No, not for pelvic mesh products,	24	ever drafted a label for a pelvic mesh	
25	no.	25	device?	
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,	Page 9.		A. No.	Page 97
1	Q. Okay. Have you done that for mesh	1	A. No.	Page 97
2	Q. Okay. Have you done that for mesh products?	1 2	Q. Outside of litigation, have you	Page 97
2	Q. Okay. Have you done that for mesh products?  A. Yes. In the context of wound	1 2 3	Q. Outside of litigation, have you ever drafted a label for a mesh device?	Page 97
2 3 4	Q. Okay. Have you done that for mesh products?  A. Yes. In the context of wound healing.	1 2 3 4	Q. Outside of litigation, have you ever drafted a label for a mesh device? A. Not a mesh device, per se. I was	Page 97
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	Pa	ge 98			Page 100
1	Q. Okay. Actually, let me break it	,	1	A. Yes.	, I
2	down a little bit more focused. Outside of		2	Q. All right. Were you on that team	
3	litigation, have you ever worked on the		3	to work on the patient brochure?	
4	adverse events section of a mesh device?		4	A. Not on the patient brochure	
5			5	specifically, no. I worked on the clinical	
	A. Not specifically, no.				
6	Q. Okay. And obviously outside of		6	information that would have gone into the	
7	litigation, have you ever worked on the		7	brochure.	
8	adverse events section of a pelvic mesh IFU?		8	Q. Okay. Would you have fed your	
9	A. No.		9	clinical information to a member on that	
10	Q. All right. Outside of litigation,		10	team	
11	have you ever worked on the warnings and		11	A. Yes.	
12	precautions section of an IFU for a mesh		12	Q for inclusion in the patient	
13	device?		13	brochure?	
14	A. No.		14	A. Yes.	
15	Q. And then even more focused, outside		15	Q. Do you know what was included in	
16	of litigation, have you ever worked on the		16	the patient brochure?	
17	warnings and precautions section of an IFU		17	A. As I sit here today, I don't recall	
18	for a pelvic mesh device?		18	specifically.	
19	A. No.		19	Q. All right.	
20	Q. Okay. Outside of litigation, have		20	A. It would have been the results of	
21	you ever worked on a patient brochure for a		21	the clinical well as I say, I put	
22	mesh device?		22	together I actually you're talking	
23	A. Are you talking about polypropylene		23	specifically about patient brochure. The	
24	mesh?		24	information, I don't recall as I sit here	
25			25	today, what would have gone into the patien	.
23	Q. I'll start with that. Do you want		23	today, what would have gone into the patien	١
	Do	aa 00			Dago 101
1		ge 99	1	brochure. I know that the information that	Page 101
1 2	me to ask it more cleanly?	ge 99	1	brochure. I know that the information that	Page 101
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Page 102 Page 104 information that was going to go to the 1 informed decision as to whether or not, 1 2 in the case of pre-marketing, in the 2 patients that were going to have a device 3 3 case of whether or not they actually implanted. 4 want to participate in a clinical trial 4 Q. And that's what you're talking 5 5 of a particular product. about, if I'm following you, is the consent 6 And I've worked on -- let me 6 that you do for them to participate in, 7 just think back a minute because it's 7 like, a clinical trial? 8 8 A. It's not just the consent. It can been over 40 years of experience. I 9 certainly have worked on information 9 also be in we call them information sheets. 10 that was to be presented in patient 10 Q. Right. But it's for participation 11 forums about particular -- particular 11 in a clinical trial? Is that the context 12 products and --12 that you're talking about? A. Yes. On the pre-clinical side, BY MS. SUTHERLAND: 13 13 yes. I'm sorry. The pre-marketing side. 14 O. I'm not sure I know what that 14 means. What do you mean "patient forums"? Q. Pre-marketing. Not pre-clinical. 15 15 A. On different seminars for patients A. Not pre-clinical. Pre-marketing 16 16 to learn more about a particular product, to 17 17 side. 18 better inform them about particular 18 Q. So to get to my question, have you sat on a copy review team that worked on a 19 products. 19 20 Certainly put together the clinical 20 patient brochure for an implantable device information that would have gone in to any after it's been cleared or in the clearance 21 21 patient -- any patient brochures. As I've 22 22 process? mentioned before, in the context of working 23 23 A. I may have. I don't recall within companies -- same as at Ethicon --24 specifically, as I sit here today. 24 they have a team. And it's not any one Q. Okay. Have you sat on such a team 25 25 Page 103 Page 105 particular person that actually puts a 1 for a patient brochure for an implantable 1 brochure together, puts the labeling 2 2 mesh device? together. The different expertises 3 3 A. No. contribute their component, and then that's 4 4 Q. All right. And I would assume, 5 pulled together typically finally by 5 then, you have not sat on such a team for a 6 regulatory for submission, but it's a team 6 patient brochure for a pelvic mesh device? 7 that puts that together. So certainly, I've 7 A. That's correct. I have not. 8 sat on those teams. 8 Q. Okay. Now, you told me that you 9 Q. Okay. Well, that's part of my 9 describe yourself as a scientist; correct? 10 question. For instance, at Ethicon, we know 10 A. Yes. I am a scientist. it's a copy -- what's called a copy review Q. Okay. And briefly -- I don't have 11 11 12 team --12 your CV in front of me. I know I've read it multiple times. Tell me why you describe 13 A. Yes. 13 Q. -- that decides the final approval yourself as a scientist. 14 14 15 of what goes into, for instance, a patient 15 A. I work -- well, first of all, let's talk about educational background. brochure; correct? 16 16 Q. Yeah. Let me start with that. 17 A. Right. 17 18 Q. Is it your testimony that you have 18 A. My educational background is in sat on similar such copy review teams for science. I have an undergraduate degree in 19 19 patient brochures for implantable devices? microbiology with -- a major in microbiology 20 20 and minors in chemistry and zoology, 21 A. For implantable devices? 21 certainly all scientific fields. My 22 O. Yes, ma'am. 22 A. For implantable devices, I have doctorate, my Ph.D. is in toxicology with a 23 23 24 done more on the pre-clinical side where 24 minor in pharmacology, again, all medical I've put together all of the patient 25 sciences. 25

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My work has involved science, including product development science, both pre-clinical testing, whether that's in vitro or in vivo testing, as well as clinical testing, all of which involve, of course, science.

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Work in manufacturing as well and ensuring that products are manufactured appropriately, according to standards. As a product manager, overseeing the start of a project from discovery all the way through to product launch and as a regulatory scientist.

- O. Do you describe yourself as a pharmacotoxicologist, or is there a particular science field that you use more frequently than others to describe yourself? Does that make sense?
- A. Well, I think I understand your question. Let me give it a try.

I describe myself as a product development expert, product development scientist, as well as a regulatory expert in regulatory sciences.

Q. Okay. All right. And --

1 and it's that entire scope and that entire

- 2 spectrum of product development which I have
- 3 over 40 years of experience in and have
- 4 directed my career to being able to
- 5 understand and evaluate and guide products
- 6 through that entire development process. 7
  - Q. Okay. And keeping that answer in mind, that entire development process, the spectrum that you just described to me, has any of your experience in that entire spectrum ever concerned a pelvic mesh product in your 40 years?
    - A. Not pelvic mesh.
  - O. Okay.
- A. Other than in the context of 15 16 litigation.
  - O. Yeah. Outside of litigation, the spectrum of experience that you just talked about on product development, that's never included a pelvic mesh product?
  - A. I have not, on the manufacturer's side, been involved in the development of a pelvic mesh product. However, all of that same level -- all of that scope, I should say, and that spectrum of experience and my

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A. Because my -- the scope of my expertise involves, as I was noting, and that's how I developed my career, from basic research all the way through to product launch and post marketing.

So my career has encompassed that entire scope of all -- when I teach, for example, I put it into different buckets, if you will, for my students to help them to understand that you have the manufacturing, the quality system component. You have the pre-clinical testing, and you have the clinical testing.

And then, of course, that all comes together in the regulatory arena in order to get a product cleared or approved, whichever the case may be, providing that the data show that it's safe and effective, and it's a quality product and that there's a favorable benefit/risk ratio, and then you 20 have the pre-marketing and the post-marketing, which should be a continuum.

As long as the product is being marketed, there's always testing and risk analysis and feedback that has to happen, experience and knowledge of all of those

- 2 areas, I applied in the context of
- 3 evaluating all of the information, the
- 4 deposition testimony, internal documents,
- 5 standards, guidance, regulation, scientific
- 6 medical literature, I applied all of that
- 7 and integrated that knowledge together to
- 8 arrive at my opinions in this case in the
- 9 very same fashion that I would for advising
- 10 clients or if employed by a company, that I
- would participate at the company as a part 11
- 12 of the product team, I apply the same type 13 of methodology.
- 14 Q. Okay. And my question, I guess, 15 was just that you have not applied that methodology outside the context of
- 16 litigation for a pelvic mesh product. 17
  - A. That's correct.
- 19 Q. Right. So a company has not asked 20 you to employ your expertise for a pelvic 21 mesh product; correct?
- A. Not for a pelvic mesh product. 22
- 23 That's correct.
- 24 Q. The only folks that have asked you 25 to apply your expertise have been plaintiff

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Page 110   A. Sorry, GLP. Good laboratory   2   A. Sorry, GLP. Good laboratory   2   A. For pelvic mesh products, yes.   3   Q. Okay. Have you ever participated   3   Q. I'm not going to talk politics with   you.   A. No.   Q. Have you ever participated in any animal study for polypropylene mesh?   A. No.   Q. Have you ever designed any clinical trials regarding polypropylene mesh?   A. I've not designed one specifically   1   A. Forry, So we could be here all   day; right? We're teasing.   So I teach GLP, and I've done   inspections of facilities to be sure that they meet the requirements for a CDF testing   facility and then help to design the unit of the sting.   A. No.   So we could be here all   day; right? We're teasing.   So I teach GLP, and I've done   inspections of facilities to be sure that they meet the requirements for a CDF testing   facility and then help to design the unit of the sting.   So I teach GLP, and I've done   inspections of facilities to be sure that they meet GLP requirements.   So I teach GLP, and I've done   inspections of facilities to be sure that they meet GLP requirements.   So I teach GLP, and I've lot doesign the unit of the facilities to make sure that they in they meet GLP requirements.   So I teach GLP, and I've lot design the testing.   So I teach GLP, and I've lot design the testing.   So I teach GLP, and I've lot doesign the unit of the facilities to make sure that they in they meet GLP requirements.   So I teach GLP, and I've lot doesign the testing.   So I teach GLP, and I've lot doesign the unit of the facilities to make sure that they're and the meet of the sting.   So I teach GLP requirements.   So I teach GLP requirements.   So I teach GLP, and I've lot doesign the testing.   So I teach GLP, and I've lot doesign the testing.   So I teach GLP, and I've lot design the testing.   So I teach GLP, and I've lot design the testing.   So I teach GLP requirements.   So I teach GL					
1 lawyers; correct? 2 A. For pelvic mesh products, yes. 3 Q. Okay. Have you ever participated 4 in any cadaver study of polypropylene mesh? 4 in any cadaver study of polypropylene mesh? 5 A. No. 6 Q. Have you ever designed any clinical 10 trials regarding polypropylene mesh? 1 A. I've not designed one specifically 10 for polypropylene mesh. I've considered 13 designs, but I've not designed one specifically 16 designs, was that outside the context of 17 litigation 18 litigation. 19 Q. All right. And when you considered 19 designs, was that outside the context of 18 litigation 19 Q. All right. Have you ever been 19 linivolved in any clinical research concerning 21 polypropylene mesh outside litigation? 2 A. No. 22 A. No. 23 Q. Have you ever done any lab work regarding polypropylene mesh? 2 A. No. 4 Q. As I understand it, your company 5 Symbion, does that have a lab? A. No. 5 Q. All right. Do you own any lab equipment? 2 equipment? 9 A. No. We work with when we're 10 working with clients, and we're working in pre-clinical research where a laboratory 2 errorizon to the study. 2 regrots, go back and forth with the contract 1 laborators to ensure that we 14 get the final report that is accurate and 2 get the final report that is accurate and 3 laboratory with questions to ensure that we 14 get the final report that is accurate and 2 get the final report that is accurate and 3 laboratory with questions to ensure that we 14 get the final report that is accurate and 2 get the final report that is accurate and 3 laboratory with questions to ensure that we 14 get the final report that is accurate and 2 get the final report that is accurate and 3 laboratory with questions to ensure that we 14 get the final report that is accurate and 2 get the final report that is accurate and 3 laboratory with questions to ensure that we 14 get the final report that is accurate and 4 get the final report that is accurate and 4 get the final report that is accurate and 4 get the final report that is accurate and 4 get the final report t		•	Page 110		Page 112
2 A. For pelvic mesh products, yes. 3 Q. Okay. Have you ever participated 4 in any cadaver study of polypropylene mesh? 5 A. No. 6 Q. Have you ever participated in any 7 animal study for polypropylene mesh? 8 A. No. 9 Q. Have you ever designed any clinical 1 trials regarding polypropylene mesh? 11 A. I've not designed one specifically 12 for polypropylene mesh. I've considered 13 designs, but I've not designed one. 14 Q. All right. And when you considered 15 designs, was that outside the context of 16 litigation? 17 A. No. It was in the context of 18 litigation? 29 Q. All right. Have you ever been 20 involved in any clinical research concerning 21 polypropylene mesh outside litigation? 22 A. No. 23 Q. Have you ever done any lab work 24 regarding polypropylene mesh? 25 A. No. 26 Q. All right. Bo you own any lab 27 equipment? 28 A. No. 29 Q. All right. Do you own any lab 29 equipment? 30 A. No. 40 Q. All right. Do you own any lab 31 equipment? 40 A. No. 41 Q. Have you ever done any lab work 42 regarding polypropylene mesh? 43 A. No. 44 You. 45 A. Sorry. So we could be here all 65 day; right? We're teasing. 6 day; right? We're teasing. 7 So I teach GLP, and I've done 8 inspections of facilities to be sure that 8 they meet the requirements for a GLP testing 6 facility and then help to design the 9 they meet the requirements for a GLP testing 16 facility and then help to design the 10 facility and then help to design the 11 facility and then help to design the 11 facility and then help to design the 12 reports, go back and forth with the contract 13 laboratory with questions to ensure that we 14 get the final report that is accurate and 15 study. 17 Q. Okay. I'm going to respectfully 18 move to strike everything after "no" because 19 I think my question was does Symbion own any 20 lab equipment? 21 A. No. 22 Q. All right. Have you ever done any 23 Q. Have you ever done any lab were 24 A. No. 25 Q. Ever done any testing of a mesh 26 A. No. 37 Q. Have you ever looked at a mesh 28 explant under a microscope? 29 A. No W	1	lawvers: correct?		1	
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		Page 114		Page 1	116
1	involved in those, yes, for mesh not	. 490	1	college.	
2	mesh. For other devices.		2	Q. I know you do. I'm doing it for	- 1
3			3	the jury and for myself.	- 1
	Q. Let me get a and I'm going to				- 1
4	ask you about DFMEA right after this one.		4	Have you ever been involved in a	- 1
5	Let me get a clean question and answer.		5	clinical trial to evaluate the safety or	- 1
6	Have you ever been involved in		6	efficacy of a medical device where part of	- 1
7	performing a device design safety analysis		7	that device was polypropylene mesh?	- 1
8	for a mesh product?		8	A. Not polypropylene, no.	- 1
9	A. No.		9	Q. All right. Have you been involved	- 1
10	Q. Have you ever reviewed a device		10	in a clinical trial to evaluate the safety	- 1
11	design safety analysis for a mesh product		11	or efficacy of a medical device where part	- 1
12	outside the context of litigation?		12	of that device was something other a mesh	- 1
13	A. No.		13	other than polypropylene mesh?	- 1
			14	A. Yes.	- 1
14	Q. Okay. Now I'll do the DFMEA.				- 1
15	A. Okay.		15	Q. And is that the Allograft that you	- 1
16	Q. Am I correct, Doctor, that an FMEA		16	talked about?	- 1
17	is a failure mode evaluation analysis?		17	A. It was in it actually was a	- 1
18	<ul> <li>A. Failure mode effects analysis.</li> </ul>		18	different product, but it was a part of the	- 1
19	Q. And have you ever performed an		19	product that was being evaluated prior to	- 1
20	DFMEA for a mesh product?		20	the final product.	- 1
21	MR. GOSS: Objection to form.		21	Q. Okay. Like a prototype?	- 1
22	THE WITNESS: Not a mesh		22	A. Yes.	- 1
23	product, no.		23	Q. Okay. What size clinical trial was	- 1
24	///		24	that?	- 1
25	BY MS. SUTHERLAND:		25	A. I don't recall, as I sit here	_
					_
		Page 115		Page 1	17
1	O All right Have you ever reviewed	Page 115	1	Page 1 today the actual numbers of natients	117
1 2	Q. All right. Have you ever reviewed	Page 115	1	today, the actual numbers of patients.	117
2	an DFMEA for a mesh product outside the	Page 115	2	today, the actual numbers of patients. Q. Do you know if it was a hundred?	117
2 3	an DFMEA for a mesh product outside the context of litigation?	Page 115	2	today, the actual numbers of patients. Q. Do you know if it was a hundred? A. If I recall correctly, it probably	117
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2 3 4 5 6	an DFMEA for a mesh product outside the context of litigation?  A. Not outside of the context of litigation.  Q. All right. Do you consider	Page 115	2 3 4 5 6	today, the actual numbers of patients. Q. Do you know if it was a hundred? A. If I recall correctly, it probably was more than that, as I sit here today without checking back. Q. Okay. Well, when was it?	117
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2 3 4 5 6 7 8	an DFMEA for a mesh product outside the context of litigation?  A. Not outside of the context of litigation.  Q. All right. Do you consider yourself an expert on how mesh performs in vivo?	Page 115	2 3 4 5 6 7 8	today, the actual numbers of patients. Q. Do you know if it was a hundred? A. If I recall correctly, it probably was more than that, as I sit here today without checking back. Q. Okay. Well, when was it? A. That particular trial was, to the best of my recollection as I sit here today,	117
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Page 118 Page 120 1 before if you had asked for that from 1 never make a recommendation. That's 2 counsel, and I thought you told me you had. something that -- I'm not a clinician. They A. To the best of my recollection, I 3 3 need to be evaluated appropriately. 4 had, and it wasn't -- it wasn't available. 4 O. By a doctor? Q. Provided? 5 5 A. By a doctor. A. Yeah. 6 6 Q. Medical doctor? 7 Q. Okay. All right. Obviously, 7 A. By a medical doctor. And based on 8 you've never diagnosed stress urinary 8 their own particular situation, what their 9 incontinence. 9 issues are, discuss with the doctor what the 10 A. No. 10 options are. It's just that if someone asks 11 Q. Have you ever treated stress 11 me, you know, "Do you know what's available? What do you think about this?" As a 12 urinary incontinence? 12 scientist, an educated scientist in this 13 A. No. 13 area, I can give them my thoughts. 14 O. Have you ever made a recommendation 14 to a woman on the options available to her But I would never make -- I would 15 15 to treat stress urinary incontinence? 16 16 never tell them what to do. That's a A. I have talked with women who -decision -- and that goes to the consenting 17 17 18 about the options that are available. 18 process that we were talking about earlier. They need to know all the information about Q. And would this have been, like, 19 19 20 friends -- I don't want names or anything. 20 the products to make an appropriate decision A. Yes. Yes. 21 for themself. 21 22 Q. About how many women have you 22 Q. For the women where you have just talked to about the options available to talked about the options for treatment of 23 23 treat stress urinary incontinence? 24 stress urinary incontinence, have you talked 24 A. Oh, it would be probably in the with them about the risks that you're aware 25 25 Page 119 Page 121 order of maybe five. 1 of with the Burch procedure? 1 2 Q. All right. And do you recall what 2 A. We really haven't gotten to that options you talked with them about? 3 3 level of detail with them. It's very A. Just told them about pessaries, 4 4 cursory conversations. 5 told them about bulking agents, told them 5 Q. Okay. Have you ever been in the about Burch colposuspension, certainly the 6 operating room when a TVT-O was actually 6 topic of pelvic mesh -- well, the mesh came 7 7 implanted? up. Clearly, I don't recommend that based 8 8 A. I've seen videos, but I've not been on everything that I've reviewed over the 9 in the operating room, yeah. last few years. So when they ask, I give 10 Q. Was it an Ethicon training video on 10 them my opinion. TVT-O that you've -- are referencing there? 11 11 A. Yes. As well -- yes. And I've 12 O. Have you recommended a Burch to a 12 looked at other videos of slings as well. 13 woman? 13 And there are even some that you can --14 A. No. I would never make a 14 15 recommendation. And, you know, and I don't 15 where certain doctors have posted various -discuss with people that -- I don't Q. Their own surgeries? 16 16 volunteer that I'm working in litigation. A. Their own, and I've looked at those 17 17 18 I'm very discreet about what I say, but if 18 as well. anybody asks me because they know I'm in --19 19 Q. Have you watched a Burch surgery? they know I'm a scientist, and clearly, you 20 A. To the best of my recollection as I 20 know, there are some people, obviously, who sit here today, I have looked at a video of 21 21 22 know that I've been at trial, that 22 that. information is available. Q. All right. Do you recall when you 23 23 24 When I'm asked, you know, I talk to 24 did that? them about the various options, but I would 25 25 A. I don't. Sometime within the last

Page 122 Page 124 couple of years -complication that has affected them a year 1 1 2 Q. Was that --2 or even two years out, these are permanent 3 implants, and it's well known and, in fact, A. -- but I don't recall specifically. 3 4 Q. I'm sorry. Was that just a video 4 Ethicon's own employees have testified that, 5 that you found off of, like, YouTube --5 for example, erosions are a lifelong risk as 6 A. Yes. 6 long as the implant is there. 7 Q. -- or was that a professional 7 And as I started to mention, in the 8 8 education video? literature, it's showing that a number of 9 A. To the best of my recollection, it 9 complications actually increase in a 10 was something that I found on YouTube. 10 percentage of patients who are 11 Q. All right. 11 experiencing -- experience them over time, which all the more supports why one needs to 12 A. And, of course, there are lots of 12 pictures, and even in the training study a permanent implant long term to see 13 13 materials, you know, for Ethicon and other what the complications may be. 14 14 places, there are pictures of procedures, And also because there is a chronic 15 15 and it discusses those procedures. So I've 16 16 foreign body reaction that is set up and certainly reviewed those. Textbooks. depending on what the mesh -- the 17 17 18 Q. All right. Let me ask you this: 18 biomaterial may be, et cetera, and the characteristics of the particular implant 19 See what I get. 19 20 A. You're going fishing? 20 may be, that long-term inflammation may also 21 Q. I'm going fishing. 21 ultimately cause complications. 22 Would you agree that there are 22 So my point being that just because patients who have had a TVT-O implanted who a woman hasn't experienced a complaint that 23 23 have had no complications? 24 has bothered her in a year doesn't mean that 24 five years from now she isn't going to have 25 A. I can't answer that as asked yes or 25 Page 125 Page 123 no because I don't know every patient that 1 one. The data supports that the data -- the 1 2 has been implanted and whether or not what 2 medium to long-term data on these products 3 complications they may or may not have had 3 is still, at this point in time, very 4 4 as well. limited. 5 It's also in the literature and 5 Q. Okay. I'm going to move to strike 6 6 everything after you finished your first documented that patients may have --7 7 sentence, and I've forgotten what that was. particularly women who are not sexually 8 active may have erosions that they're not 8 Let me ask it this way: Do you aware of, and without an actual pelvic 9 intend to offer an opinion that every woman 10 examination, physical examination, that that 10 implanted with a TVT-O will have a can't be -- that may not be detected. So complication from that mesh? 11 11 for several reasons, I'm unable to say yes MR. GOSS: Objection to form. 12 12 or no the way your question was asked. THE WITNESS: I can't say they 13 13 Q. Okay. Let me ask a couple of will. What I can say is that there is a 14 14 15 follow-ups. It's correct, then, that a 15 potential for complication. So they may woman can have an erosion and be completely not. They may not. 16 16 BY MS. SUTHERLAND: asymptomatic; correct? 17 17 18 A. In the situation that I described 18 Q. All right. You mentioned before where she isn't sexually active, and it's -the need for long-term clinical data for 19 19 it's small, it may not be bothering her, is permanent implants. 20 20 my understanding as I sit here today. It 21 21 A. Yes. 22 doesn't mean that it may not bother her long 22 Q. And I know I've asked you this term, and that also is an important point before, and I don't think you gave me a 23 23 specific time frame a couple of weeks ago 24 because what we're seeing in the literature 24 is that just because a patient hasn't had a 25 when I asked this. Do you have a specific 25

	Page 126		Page 128
1	time frame in mind today that, in your	1	your opinions.
2	opinion, constitutes what you call long-term	2	Would you agree that there are
3	for a permanent implant?	3	women where the TVT-O has been placed where
4	MR. GOSS: Objection to form.	4	it's been effective to treat their stress
5	THE WITNESS: In the	5	
			urinary incontinence?
6	literature	6	MR. GOSS: Objection. Form.
7	BY MS. SUTHERLAND:	7	THE WITNESS: Based on my
8	Q. Let me ask a better question	8	understanding, that's correct.
9	because that was so convoluted I lost it.	9	BY MS. SUTHERLAND:
10	A. Okay.	10	Q. All right. Would you agree that
11	Q. As I understand your opinion, it's	11	there are a lot of doctors in the United
12	that for a permanent implant such as the	12	States who believe that the TVT-O is safe
13	TVT-O, a manufacturer needs long-term data;	13	and effective?
14	is that right?	14	MR. GOSS: Objection. Form.
15	A. Yes. Yes.	15	THE WITNESS: Based on my
16	Q. All right. Now, do you have a	16	knowledge of the situation today, there
17	specific time frame that you're ascribing to	17	are doctors who, yes, believe it is safe
18	"long-term data"?	18	and effective. There are others who are
19	A. A medium term is three to five	19	changing their opinions.
20	years. Long-term would be ten years.	20	BY MS. SUTHERLAND:
21	Q. Okay. And is it your opinion	21	Q. Okay. Other than the Burch
22	that	22	procedure, are there other surgical
23			•
	A. Or longer than five years but at	23	procedures that you're aware of for the
24	least ten years would be helpful.	24	treatment of stress urinary incontinence
25	Q. All right.	25	without the use of mesh?
	D 427		D 422
,	Page 127	1	Page 129
1	A. And that is also described in some	1	A. Yes.
2	pieces of literature.	2	Q. Okay. And what are they?
3	Q. So is it five years, or is it ten	3	A. Well, the Burch can be done open or
4	years?	4	laparoscopically. There's the MMK, the
5	A. Three to five for mid, for medium.	5	Marshall-Marchetti-Krantz. Paravaginal
6	Ten years would be long-term for a permanent	6	repairs, different types of suspensions and,
7	implant.	7	of course, then there are you said
8	Q. Okay. And so for a permanent	8	surgical, though; right?
9	implant like the TVT-O, are you going to	9	Q. Yes, ma'am.
10	offer an opinion at trial that Ethicon	10	<ul> <li>A. So excluding bulking agents.</li> </ul>
11	should have had ten years worth of data	11	Q. Yeah. When you talk about
12	before they marketed the TVT-O?	12	suspensions, are you talking about the use
13	A. No, because that becomes that	13	of an autologous sling as well?
14	there's a practicality aspect, obviously, as	14	A. Yes, definitely an autologous sling
15	well. What they should have done, however,	15	or an Allograft as well.
16	is to continue a registry and have follow-on	16	Q. Yeah. By "Allograft," do you mean
17	data so that they're collecting that data.	17	either cadaver or some kind of animal?
18	But before you even get to that point, there	18	A. Well, that would be a xenograft,
19	is a lot of testing that should have been	19	but yeah. So cadaver tissue, yes. There
	is a loc or costing that should have been		• • • • • • • • • • • • • • • • • • • •
/!!	done pre-marketing that they didn't do that	711	are different outlone as well as the
20 21	done pre-marketing that they didn't do that	20 21	are different options as well as the
21	they should have understood before these	21	autologous grafts.
21 22	they should have understood before these products were implanted in women.	21 22	autologous grafts. Q. All right. Now, are you familiar
21 22 23	they should have understood before these products were implanted in women.  Q. And I'm going to get to that	21 22 23	autologous grafts. Q. All right. Now, are you familiar
21 22 23 24	they should have understood before these products were implanted in women.  Q. And I'm going to get to that because that's one of your opinions in your	21 22 23 24	autologous grafts. Q. All right. Now, are you familiar A. Autologous sling, I should say.
21 22 23	they should have understood before these products were implanted in women.  Q. And I'm going to get to that	21 22 23	autologous grafts. Q. All right. Now, are you familiar

1 A. I'm sorry. 2 Q. I don't mean to cut you off. 3 Are you familiar with the risks 4 associated with those different procedures 5 that you just mentioned? 6 A. I think so, yes. 7 Q. All right. So with respect to the 8 Burch open procedure, can you tell me what 9 are the risks associated with that 10 procedure? 11 A. Well, certainly you have  Page 130  1 about a foreign body, there are the differences where there's where the differences w	ere's a ogical a
1 about a foreign body, there are the 2 differences where there's where the 3 Are you familiar with the risks 4 associated with those different procedures 5 that you just mentioned? 5 obviously don't have in the Burch 6 A. I think so, yes. 7 Q. All right. So with respect to the 8 Burch open procedure, can you tell me what 9 are the risks associated with that 10 procedure? 1 about a foreign body, there are the 2 differences where there's where the 3 graft being placed. Even with a biolo 4 graft, you can get erosion that you 5 obviously don't have in the Burch 6 colposuspension. 7 Q. And did you say can you have 8 foreign body reaction when you use a 9 body other than a mesh? 10 A. Well, I'm speaking more there	ere are nere's a ogical a
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3 Graft being placed. Even with a biolo 4 associated with those different procedures 5 that you just mentioned? 6 A. I think so, yes. 7 Q. All right. So with respect to the 8 Burch open procedure, can you tell me what 9 are the risks associated with that 10 procedure? 3 graft being placed. Even with a biolo 4 graft, you can get erosion that you 5 obviously don't have in the Burch 6 colposuspension. 7 Q. And did you say can you have 8 foreign body reaction when you use a body other than a mesh? 10 A. Well, I'm speaking more there	ogical a
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9 are the risks associated with that 9 body other than a mesh? 10 procedure? 10 A. Well, I'm speaking more there	a foreign 💎 📗
10 procedure? 10 Å. Well, I'm speaking more there	-
11 A. Well, certainly you have 11 the polypropylene meshes.	about
12 MR. GOSS: Objection. Form. 12 Q. Okay. I'm excluding the mesh	es for
13 THE WITNESS: the same risk 13 right now.	
14 of anesthesia that you do with any 14 A. Okay.	
surgical procedure. There's the risk of 15 Q. I'm just wanting to get your	
pain, pelvic pain, the risk of 16 understanding of the risks that are	
dyspareunia, the risk of bleeding, the 17 attendant to, for instance, that you sa	aid an
18 risk of organ perforation, the risk of 18 autologous sling for the treatment of	
19 voiding dysfunction. Those are some of 19 MR. GOSS: Objection. Form	
20 the representative ones. 20 THE WITNESS: That's one's	
21 BY MS. SUTHERLAND: 21 tissue.	5 OWII
22 Q. And I had asked that specific to 22 BY MS. SUTHERLAND:	
· '	odo2
1 ,	
24 applicable, for instance, to the Burch 24 MR. GOSS: Objection. Form	n.
25 performed laparoscopically? 25 BY MS. SUTHERLAND:	
Page 121	Page 122
Page 131 1 A. Yes. 1 Q. Or do you know?	Page 133
2 Q. And would those same risks be 2 MR. GOSS: Objection. Form	_
3 applicable to the MMK? 3 THE WITNESS: I haven't	''.
· ·	a+
5 correct. 5 it could, but I haven't actually stud	ileu
6 MR. GOSS: Objection. Form. 6 that.	
7 BY MS. SUTHERLAND: 7 BY MS. SUTHERLAND:	
8 Q. Okay. Do you know how many doctors 8 Q. Can the sutures that are utilize	
9 perform the MMK today? 9 in these other surgical procedures for	r the
10 A. I don't know how many doctors. 10 treatment of SUI erode?	
11 It's my understanding that it's not 11 A. Yes.	
12 performed very often today. 12 Q. And can you have a reaction to	o the
13 Q. Okay. Do you know if it's even 13 use of cadaver tissue?	
14 taught in medical school anymore? 14 MR. GOSS: Objection. Form	
14 taught in medical school anymore?14MR. GOSS: Objection. Form.15MR. GOSS: Objection. Form.15THE WITNESS: You could, when the country is a country is a country is a country in the country in the country is a country in the country in the country is a country in the country in th	yes.
14 taught in medical school anymore? 14 MR. GOSS: Objection. Form	yes.
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14taught in medical school anymore?14MR. GOSS: Objection. Form.15MR. GOSS: Objection. Form.15THE WITNESS: You could, you	d you use m.
14taught in medical school anymore?14MR. GOSS: Objection. Form.15MR. GOSS: Objection. Form.15THE WITNESS: You could, or the WITNESS: You could, or the WITNESS: I can't say for16THE WITNESS: I can't say for16BY MS. SUTHERLAND:17every medical school whether or not it's17Q. I mean, that's a risk associated with surgical treatment of SUI where19evaluation.19cadaver tissue, isn't it?20BY MS. SUTHERLAND:20MR. GOSS: Objection. Form21Q. All right. Would those same risks21THE WITNESS: It's a potential.	d you use m.
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	•	Page 134			Page 136
1	What, if anything, have you done to		1	treatment of SUI that does not use mesh?	
2	determine whether doctors knew of these		2	MR. GOSS: Objection. Form.	
3	risks for surgical treatment of SUI other		3	THE WITNESS: Yes. And more	
4	than with mesh?		4	specifically, the labeling should	
5	MR. GOSS: Objection. Form.		5	include information about frequency,	
	THE WITNESS: If I understand				
6			6	severity, chronicity of those particular	
7	your question correctly, review of the		7	risks.	
8	literature, review of textbooks about		8	BY MS. SUTHERLAND:	
9	the procedure, review of deposition		9	Q. Okay. And I'm going to get to	
10	testimony. I think that's probably a		10	that. So I'm going to move to strike	
11	good summation.		11	everything after "yes" for right now.	
12	BY MS. SUTHERLAND:		12	Well, I'll go ask you this while	
13	Q. Okay. Have you done any kind of		13	we're on that. Is there any IFU that you've	
14	survey of physicians to understand their		14	seen for a pelvic mesh device that includes	
15	state of knowledge with respect to the risks		15	rates of frequency for their adverse events?	
16	you've listed for surgical options for the		16	MR. GOSS: Objection. Form.	
17	treatment of SUI other than with mesh?		17	THE WITNESS: Not for a pelvic	
18	MR. GOSS: Objection. Form.		18	mesh device of the ones that I have	
19	THE WITNESS: I've not done a		19	reviewed that we discussed earlier.	
20			20	BY MS. SUTHERLAND:	
	SURVEY, NO.				
21	BY MS. SUTHERLAND:		21	Q. Of the ones you've reviewed, yeah.	
22	Q. All right. So if I'm understanding		22	What about any mesh device? Does	
23	you correctly let me ask you this: Would		23	any mesh device that you've reviewed, does	
24	it be fair to say that you are aware of		24	the IFU include frequency rates for their	
25	these risks because of your review of the		25	adverse events?	
1	modical literature?	Page 135	1	MD COSS: Objection Form	Page 137
1	medical literature?	Page 135	1	MR. GOSS: Objection. Form.	Page 137
2	A. Yes.	Page 135	2	THE WITNESS: If I recall	Page 137
2	A. Yes. MR. GOSS: Objection. Form.	Page 135	2	THE WITNESS: If I recall correctly as I sit here today, for	Page 137
2 3 4	A. Yes. MR. GOSS: Objection. Form. BY MS. SUTHERLAND:	Page 135	2 3 4	THE WITNESS: If I recall correctly as I sit here today, for example, some of the Gor-Tex IFUs	Page 137
2 3 4 5	A. Yes. MR. GOSS: Objection. Form. BY MS. SUTHERLAND: Q. All right. Is it your opinion that	Page 135	2 3 4 5	THE WITNESS: If I recall correctly as I sit here today, for example, some of the Gor-Tex IFUs include clinical data that shows the	Page 137
2 3 4 5 6	A. Yes. MR. GOSS: Objection. Form. BY MS. SUTHERLAND: Q. All right. Is it your opinion that doctors are aware of these risks if they	Page 135	2 3 4 5 6	THE WITNESS: If I recall correctly as I sit here today, for example, some of the Gor-Tex IFUs include clinical data that shows the frequency of particular adverse events	Page 137
2 3 4 5 6 7	A. Yes. MR. GOSS: Objection. Form. BY MS. SUTHERLAND: Q. All right. Is it your opinion that doctors are aware of these risks if they have reviewed the medical literature?	Page 135	2 3 4 5 6 7	THE WITNESS: If I recall correctly as I sit here today, for example, some of the Gor-Tex IFUs include clinical data that shows the frequency of particular adverse events in the clinical testing.	Page 137
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Yes.  MR. GOSS: Objection. Form. BY MS. SUTHERLAND: Q. All right. Is it your opinion that doctors are aware of these risks if they have reviewed the medical literature?  MR. GOSS: Objection. Form.  THE WITNESS: Yes. And they were also taught. BY MS. SUTHERLAND: Q. In medical school? A. In medical school or more specifically in their fellowships or internships and fellowships, residencies. Q. Now. Is it your opinion that a manufacturer of a mesh device for the surgical treatment of stress urinary incontinence has a duty to warn of risks associated with the use of the device?  A. Yes. Q. All right. Now, in your definition of risks associated with the use of the	Page 135	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	THE WITNESS: If I recall correctly as I sit here today, for example, some of the Gor-Tex IFUs include clinical data that shows the frequency of particular adverse events in the clinical testing.  BY MS. SUTHERLAND:  Q. Okay. And would that be a separate section under clinical performance in that IFU?  A. To the best of my recollection, yes, it's included there. But it's present in the IFU.  Q. And, now, I'm assuming your opinion well, let me just ask you: Is your opinion that in the IFU Ethicon, under the adverse events section where it listed adverse events, it should have listed frequency rates for those adverse events?  A. They should have let me go back to the purpose of labeling, which is to provide the information to the physician	Page 137

	Page 138			Page 140
1	said, you know, he wanted if I recall	1	you guys want to break for lunch?	
2	correctly, he wanted to make an informed	2	MR. GOSS: How about now?	
3	decision, and information to make an	3	Whenever you're at a stopping point.	
4	informed decision includes, because just as	4	MS. SUTHERLAND: I mean, I	
5	you've mentioned there, some of the same	5	think I'm at a good enough now as	
6	types of side effects, risks that occur with	6	later.	
7	the mesh products can occur with other types	7	MR. GOSS: All right.	
8	of surgery as well.	8	THE VIDEOGRAPHER: All right.	
9	So in order to make an informed	9	With the approval of counsel, going off	
10	decision about what is the appropriate	10	the record. The time is approximately	
11	alternative for this woman, like in the case	11	12:15 p.m.	
12	of Ms. Ramirez, her case, a 28 years old,	12	Lunch recess taken from	
13	whether or not you implant a mesh product or	13	12:15 p.m. to 1:01 p.m.)	
14	use something else, understanding the	14	THE VIDEOGRAPHER: With the	
15	frequency, the severity, the permanency,	15	approval of counsel, back on the record.	
16	chronicity of these in contrast to other	16	The time is approximately 1:01 p.m.	
17	procedures where there may be there's a	17	BY MS. SUTHERLAND:	
18	possibility or the potential for adverse	18	Q. Dr. Pence, welcome back from lunch.	
19	effects but that don't have the same level	19	A. Thank you.	
20	of severity, or they don't occur as often,	20	Q. I wanted to follow up on what we	
21	and they don't last as they don't last	21	had kind of been talking about before the	
22	chronically for the lifetime of the patient.	22	break, which was your opinion that there	
23	And then, of course, you have the	23	needs to be frequency rates set out beside	
24	specific mesh-related complications as well.	24	adverse events in the IFU.	
25	But yes, and if you look at the G91-1, the	25	A. Yes.	
	Page 139			Page 141
1	Page 139 Blue Book Memo, it does address that you	1	Q. All right. And if I understood you	Page 141
1 2	Blue Book Memo, it does address that you should actually list the adverse events in	1 2	Q. All right. And if I understood you correctly, you were relying on the Blue Book	Page 141
	Blue Book Memo, it does address that you should actually list the adverse events in order of greatest clinical significance and			Page 141
2 3 4	Blue Book Memo, it does address that you should actually list the adverse events in order of greatest clinical significance and where appropriate, you have from clinical	2	correctly, you were relying on the Blue Book	Page 141
2 3 4 5	Blue Book Memo, it does address that you should actually list the adverse events in order of greatest clinical significance and where appropriate, you have from clinical information frequency that that should be	2	correctly, you were relying on the Blue Book Memo for that opinion?	Page 141
2 3 4 5 6	Blue Book Memo, it does address that you should actually list the adverse events in order of greatest clinical significance and where appropriate, you have from clinical information frequency that that should be included as well.	2 3 4	correctly, you were relying on the Blue Book Memo for that opinion? A. Yes.	Page 141
2 3 4 5 6 7	Blue Book Memo, it does address that you should actually list the adverse events in order of greatest clinical significance and where appropriate, you have from clinical information frequency that that should be included as well.  MS. SUTHERLAND: All right.	2 3 4 5	correctly, you were relying on the Blue Book Memo for that opinion? A. Yes. Q. All right. And I where did it	Page 141
2 3 4 5 6 7 8	Blue Book Memo, it does address that you should actually list the adverse events in order of greatest clinical significance and where appropriate, you have from clinical information frequency that that should be included as well.  MS. SUTHERLAND: All right. Would you read my question back.	2 3 4 5 6	correctly, you were relying on the Blue Book Memo for that opinion? A. Yes. Q. All right. And I where did it just go? Oh.	Page 141
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Blue Book Memo, it does address that you should actually list the adverse events in order of greatest clinical significance and where appropriate, you have from clinical information frequency that that should be included as well.  MS. SUTHERLAND: All right.  Would you read my question back.  (Record read by the reporter as follows: Is it your opinion that in the IFU Ethicon under the adverse events section where it listed adverse events it should have listed frequency rates for those adverse events?") BY MS. SUTHERLAND:  Q. And I'm if I missed your answer, I apologize, but I do want an answer to that question if I could get it.  A. Yes, that's my opinion.  Q. Okay. Now  MR. GOSS: You missed that in the last answer?  MS. SUTHERLAND: I missed that one. You saw how long she had to scroll	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	correctly, you were relying on the Blue Book Memo for that opinion?  A. Yes. Q. All right. And I where did it just go? Oh. A. As well as experience. Q. Okay. And in case I didn't ask this before, is there any pelvic mesh IFU that you have reviewed that lists frequency rates outside adverse events? A. No. Q. Okay. Now, in looking at the Blue Book Memo, which I marked as Exhibit Number 2 A. I might also add that in addition to the Blue Book Memo, there's also the GHTF labeling document, which talks about all residual risk, and we may have talked about in the prior deposition that risk is a combination of the probability of occurrence and severity. Q. Well, the probability of occurrence	

	Page 142		Page	e 144
1	A. That's the definition of risk, yes.	1	MS. SUTHERLAND: No, I haven't.	
2	It's a combination of those.	2	Certainly you're welcome to if you want	
3	Q. Now, the GHTF labeling guidance	3	to as Exhibit 9.	
4	does not set out anything about listing	4	If you don't mind sticking that	
5	frequency next to adverse events, does it?	5	on there. That means you've got to give	
6	MR. GOSS: Objection. Form.	6	it up.	
7	THE WITNESS: It talks about	7	(Exhibit Number 9 was	
8	let me just refresh my recollection	8	marked for identification.)	
9	MS. SUTHERLAND: Okay.	9	MR. GOSS: That's how you lost	
10	THE WITNESS: but it says	10	your last one; right?	
11	that all residual risk, and risk by	11	THE WITNESS: Yes. Exactly.	
12	definition includes a combination of	12	MS. SUTHERLAND: This was his	
13	probability of occurrence and severity.	13	idea.	
14	And some of these documents, you know,	14	BY MS. SUTHERLAND:	
15	various pieces of literature also	15	Q. So if I'm right, are you relying on	
16	•	16		
17	discuss, in addition to the guidances,	17	the GHTF labeling guidance and the Blue Book	
	discuss severity as being important.		Memo for your opinion that frequency rates	
18	BY MS. SUTHERLAND:	18	need to be listed out beside adverse events	
19	Q. And when you get to the document,	19	in a pelvic mesh IFU?	
20	tell me what you're looking at, please.	20	A. Yes. As well as I mentioned my own	
21	A. Okay. This is the label	21	experience and also the fact that, if I'm	
22	instructions for use in medical devices.	22	recalling correctly as I sit here today,	
23	Q. Okay.	23	that Ethicon's corporate designee testified,	
24	A. GHTF guidance.	24	regulatory corporate designee Susan Lin,	
25	Q. Right.	25	testified, again as I recall, if I recall	
	Page 143	_		e 145
1	A. Which states that "Residual risks,	1	correctly as I sit here today, that Ethicon	e 145
2	A. Which states that "Residual risks, which are required to be communicated to the	2	correctly as I sit here today, that Ethicon had adopted the G91-1 as its standard.	e 145
2	A. Which states that "Residual risks, which are required to be communicated to the user and/or other person, should be included	2 3	correctly as I sit here today, that Ethicon had adopted the G91-1 as its standard. Q. Okay. Well, let's look at the Blue	e 145
2 3 4	A. Which states that "Residual risks, which are required to be communicated to the user and/or other person, should be included as limitations, contraindications,	2 3 4	correctly as I sit here today, that Ethicon had adopted the G91-1 as its standard. Q. Okay. Well, let's look at the Blue Book Memo, which you're calling the G91-1	e 145
2 3 4 5	A. Which states that "Residual risks, which are required to be communicated to the user and/or other person, should be included as limitations, contraindications, precautions, or warnings in the labeling."	2 3 4 5	correctly as I sit here today, that Ethicon had adopted the G91-1 as its standard. Q. Okay. Well, let's look at the Blue Book Memo, which you're calling the G91-1 standard; correct?	e 145
2 3 4 5 6	A. Which states that "Residual risks, which are required to be communicated to the user and/or other person, should be included as limitations, contraindications, precautions, or warnings in the labeling."  MR. GOSS: Let the record	2 3 4 5 6	correctly as I sit here today, that Ethicon had adopted the G91-1 as its standard. Q. Okay. Well, let's look at the Blue Book Memo, which you're calling the G91-1 standard; correct? A. Right.	e 145
2 3 4 5 6 7	A. Which states that "Residual risks, which are required to be communicated to the user and/or other person, should be included as limitations, contraindications, precautions, or warnings in the labeling."	2 3 4 5 6 7	correctly as I sit here today, that Ethicon had adopted the G91-1 as its standard. Q. Okay. Well, let's look at the Blue Book Memo, which you're calling the G91-1 standard; correct? A. Right. Q. And if you'll turn to the adverse	e 145
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2 3 4 5 6 7 8 9	A. Which states that "Residual risks, which are required to be communicated to the user and/or other person, should be included as limitations, contraindications, precautions, or warnings in the labeling."  MR. GOSS: Let the record reflect that the witness is reading from page  THE WITNESS: Unfortunately, it doesn't have a page number.	2 3 4 5 6 7 8 9	correctly as I sit here today, that Ethicon had adopted the G91-1 as its standard.  Q. Okay. Well, let's look at the Blue Book Memo, which you're calling the G91-1 standard; correct?  A. Right.  Q. And if you'll turn to the adverse event section in there, and I pulled down the page, down at the bottom, do you see where	e 145
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					1
		Page 146			Page 148
1	language, you're looking under adverse	-	1	Q. And now I understand and I'm going	·
2	reactions under Section 8 of the Blue Book		2	to get to your opinion about listing	
3	Memo?		3	additional adverse reactions. Right now my	
4	A. Yes.		4	question to you is: The adverse reactions	
5	Q. And you're looking under the third		5	that are listed there, is it your opinion	
6	paragraph that begins "Adverse reactions		6	that they are not listed in descending order	
7	should be listed"?		7	according to their clinical significance?	
8	A. Yes.		8	Actually, strike that. Let me ask a	
9	Q. All right. Is this what you're		9	different question to begin with, and then	
10	the standard that you're relying on when you		10	I'll come back to that.	
11	opine that "Adverse reactions should be		11	MR. GOSS: As long as I haven't	
12	listed in descending order according to		12	marked on that Blue Book, you can mark	
13	their clinical significance as determined by		13	that as an exhibit if you want.	
14	their severity and frequency"?		14	MS. SUTHERLAND: Well, I marked	
15	A. Correct.		15	hers as the Blue Book.	
16	Q. All right. And let me ask you		16	MR. GOSS: Okay.	
17	I'm going to had you the TVT-O IFU that I'm		17	MS. SUTHERLAND: Yeah.	
				BY MS. SUTHERLAND:	
18 19	going to mark as Exhibit Number 10.		18		
	(Exhibit Number 10 was		19	Q. You're not a medical doctor;	
20	marked for identification.)		20	correct?	
21	BY MS. SUTHERLAND:		21	A. That's correct.	
22	Q. And I have marked on mine		22	Q. And you don't implant mesh	
23	MR. GOSS: Don't worry about		23	obviously; correct?	
24	it. What is that?		24	A. Correct.	
25	MS. SUTHERLAND: It's just the		25	Q. And you don't treat complications	
		Daga 147			Dago 140
1	TELL	Page 147	1	accordated with the use of mesh, correct?	Page 149
1 2	IFU.	Page 147	1	associated with the use of mesh; correct?	Page 149
2	BY MS. SUTHERLAND:	Page 147	2	A. That's correct.	Page 149
2	BY MS. SUTHERLAND: Q. And I want you to turn with me,	Page 147	2	<ul><li>A. That's correct.</li><li>Q. Or with surgical procedures to</li></ul>	Page 149
2 3 4	BY MS. SUTHERLAND: Q. And I want you to turn with me, Doctor, to the adverse reaction section.	Page 147	2 3 4	A. That's correct. Q. Or with surgical procedures to treat stress urinary incontinence; correct?	Page 149
2 3 4 5	BY MS. SUTHERLAND: Q. And I want you to turn with me, Doctor, to the adverse reaction section. A. Is this the IFU that was in use	Page 147	2 3 4 5	<ul><li>A. That's correct.</li><li>Q. Or with surgical procedures to treat stress urinary incontinence; correct?</li><li>A. That's correct.</li></ul>	Page 149
2 3 4 5 6	BY MS. SUTHERLAND: Q. And I want you to turn with me, Doctor, to the adverse reaction section. A. Is this the IFU that was in use with Ms. Ramirez?	Page 147	2 3 4 5 6	<ul><li>A. That's correct.</li><li>Q. Or with surgical procedures to treat stress urinary incontinence; correct?</li><li>A. That's correct.</li><li>Q. So do you consider yourself</li></ul>	Page 149
2 3 4 5 6 7	BY MS. SUTHERLAND: Q. And I want you to turn with me, Doctor, to the adverse reaction section. A. Is this the IFU that was in use with Ms. Ramirez? Q. I pulled it from Dr. Reyes'	Page 147	2 3 4 5 6 7	<ul> <li>A. That's correct.</li> <li>Q. Or with surgical procedures to treat stress urinary incontinence; correct?</li> <li>A. That's correct.</li> <li>Q. So do you consider yourself qualified to opine as to the clinical</li> </ul>	Page 149
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		Page 150		Page	152
1	is determined, like within the project		1	known through commercial experience, the	
2	team, with based on a clinical		2	scientific literature, clinical	
3	evaluation which includes commercial		3	investigations that are done.	
4	experience. It includes what's in the		4	And when you look at the	
5	clinical literature and clinical		5	potential whether the where	
6	investigations.		6	there's a reasonable association of the	
7	And as a part of my career in		7	device with the occurrence of the event,	
8	product development, yes, I have often		8	there doesn't have to be causation	
9	evaluated adverse reactions as regards		9	proved. Based on that analysis, you	
10	to clinical significance and working		10	determine what should go in the	
11			11	labeling, which I did for my opinions,	
	with investigators to make that			- · · · · · · · · · · · · · · · · · · ·	
12	determination.		12	and yes, I am qualified to do that.	
13	But I've done evaluations of		13	BY MS. SUTHERLAND:	
14	adverse reactions for clinical		14	Q. Okay. And my question is not	
15	significance myself, but we incorporate		15	asking you if you're qualified to opine as	
16	physicians as a part of that product		16	to what ought to be in the labeling. My	
17	team.		17	question is: Are you qualified as a	
18	But the labeling here, if you		18	non-physician to tell me of the adverse	
19	read what this says, it says, "Provide		19	events that are in the labeling, which are	
20	frequency data from adequate clinical		20	more clinically significant than others as	
21	studies." So it's from the clinical		21	far as the order that they ought to be	
22	evaluation, which I've participated in		22	listed?	
23	many times, that you based on the		23	MR. GOSS: Objection. Form,	
24	different types of clinical data, you		24	asked and answered.	
25	determine what's clinically significant.		25	THE WITNESS: With severity and	
_	December health?	Page 151		Page	153
1	Does that help?	Page 151	1	frequency, based on severity and	153
2	BY MS. SUTHERLAND:	Page 151	2	frequency, based on severity and frequency, yes. In terms of whether or	153
2 3	BY MS. SUTHERLAND: Q. Not really. Right now my question	Page 151	2	frequency, based on severity and frequency, yes. In terms of whether or not a clinician thinks in terms of	153
2 3 4	BY MS. SUTHERLAND: Q. Not really. Right now my question is just on are you do you consider	Page 151	2 3 4	frequency, based on severity and frequency, yes. In terms of whether or not a clinician thinks in terms of managing a patient one is more important	153
2 3 4 5	BY MS. SUTHERLAND: Q. Not really. Right now my question is just on are you do you consider yourself qualified as a non-physician to	Page 151	2 3 4 5	frequency, based on severity and frequency, yes. In terms of whether or not a clinician thinks in terms of managing a patient one is more important than another, then for that, a physician	153
2 3 4 5 6	BY MS. SUTHERLAND: Q. Not really. Right now my question is just on are you do you consider yourself qualified as a non-physician to offer an opinion as to the clinical	Page 151	2 3 4 5 6	frequency, based on severity and frequency, yes. In terms of whether or not a clinician thinks in terms of managing a patient one is more important than another, then for that, a physician would be the appropriate person. But in	153
2 3 4 5 6 7	BY MS. SUTHERLAND: Q. Not really. Right now my question is just on are you do you consider yourself qualified as a non-physician to offer an opinion as to the clinical significance of the different adverse	Page 151	2 3 4 5 6 7	frequency, based on severity and frequency, yes. In terms of whether or not a clinician thinks in terms of managing a patient one is more important than another, then for that, a physician would be the appropriate person. But in terms of severity and frequency on	153
2 3 4 5 6 7 8	BY MS. SUTHERLAND: Q. Not really. Right now my question is just on are you do you consider yourself qualified as a non-physician to offer an opinion as to the clinical significance of the different adverse reactions that are set out in the TVT-O IFU?	Page 151	2 3 4 5 6 7 8	frequency, based on severity and frequency, yes. In terms of whether or not a clinician thinks in terms of managing a patient one is more important than another, then for that, a physician would be the appropriate person. But in terms of severity and frequency on clinical significance, yes.	153
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Page 154 Page 156 Q. Do you with that? 1 agree to disagree on your qualifications on 1 2 that, but assuming you are allowed to opine 2 A. Yes. as to the clinical significance of adverse 3 3 Q. All right. The device user for a 4 reactions, in looking at the TVT-O IFU, are 4 pelvic mesh product is someone who's been 5 5 those adverse reactions listed appropriately trained in the surgical treatment of stress in descending order according to their 6 urinary incontinence; correct? 6 7 clinical significance as determined by their 7 A. In the treatment of stress -- well, 8 severity and frequency? 8 we hope so, yes. MR. GOSS: Objection. Form. 9 9 Q. Well, the information -- I mean, THE WITNESS: There are no 10 10 the IFU, in fact, sets out that that's who 11 severities and frequencies listed here 11 ought to be using the TVT-O; correct? A. Yes. 12 to denote that aspect of whether or not 12 they're listed in order of clinical 13 13 Q. Someone who's been trained in the significance. surgical treatment of stress urinary 14 14 As well, some of them are 15 15 incontinence? wrong, like transitory foreign body 16 16 A. That is correct. reaction may occur. It may be chronic. Q. And, in fact, someone who's been 17 17 18 BY MS. SUTHERLAND: 18 trained in the use of the TVT-O; right? I mean, that's what the IFU says, isn't it? 19 Q. Do you have an opinion that you 19 20 intend to give that the adverse reactions 20 A. Let me look at the specific that are listed in the TVT-O IFU are 21 language. 21 22 incorrectly listed as far as being put in 22 Q. Okay. It's actually on page 2 descending order according to their clinical under "Important." 23 23 A. Yes, it does. This one does say 24 significance as determined by their severity 24 and specifically in implanting the Gynecare 25 and frequency? 25 Page 155 Page 157 MR. GOSS: Objection. Form. 1 TVT obturator device. That said --1 2 THE WITNESS: As regards to the 2 Q. Well, now, you've answered my 3 question as you've asked it and as I 3 question. So my next question is -understand it, that's not my intention MR. GOSS: Let me see that. 4 4 5 to opine about that specifically. 5 BY MS. SUTHERLAND: 6 BY MS. SUTHERLAND: 6 Q. Have you conducted a study of 7 O. Okay. Then let me take you to the 7 surgeons who are trained in the surgical 8 next sentence on the Blue Book Memo, and it 8 use -- strike that. talks about "Provide frequency data from 9 Have you conducted a survey of adequately reported clinical studies when 10 physicians who have been trained in the 10 the data is not well known to the device surgical treatment of SUI and trained in the 11 11 user and/or when needed in deciding between use of TVT-O to determine whether or not 12 12 they were unaware of frequency data of any the use of the device and an alternative 13 13 procedure or approach." 14 14 adverse event? 15 Are you with me? 15 MR. GOSS: Objection. Form. MS. VERBEEK: Same objection. 16 A. Yes. 16 THE WITNESS: I have not Q. All right. I want to break those 17 17 18 into two questions, if I could, first. 18 conducted a survey, but I've certainly As I understand what the Blue Book reviewed deposition testimony where 19 19 20 Memo says, it says you provide frequency 20 there's information about adverse data from adequately reported clinical reactions or potential adverse reactions 21 21 studies when the data is not well known to 22 22 that doctors were not aware of. the device user. All right? Are you with 23 23 /// BY MS. SUTHERLAND: 24 me? 24 25 25 Q. And how many depositions of A. Yes. Yes.

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1	surgeons trained in the surgical treatment	1	effective use of the product, and if you	
2	of SUI and TVT-O have you reviewed?	2	don't include information from clinical	
3	MR. GOSS: Objection. Form.	3	studies for very adverse events that are	
4	THE WITNESS: I don't have a	4	of high clinical significance in the	
5	specific number that I recall as I sit	5	labeling, then you are assuming that	
6	here today.	6	those 30 some-odd thousand physicians	
7	BY MS. SUTHERLAND:	7	who could potentially use the product	
		8	have all read all the literature that	
8	Q. I mean, it's less than five.			
9	Wouldn't that be fair?	9	expresses that important information.	
10	A. It may be more than five.	10	And you're also assuming, then,	
11	Q. Of surgeons trained for TVT-O?	11	that all of those 30 some-odd thousand	
12	A. It may be more than five.	12	doctors have gone to specific training	
13	Q. Is it going to be more than ten?	13	for TVT-O, and the TVT-O training is a	
14	MR. GOSS: Objection. Form.	14	cadaver lab sometimes with a proctor	
15	THE WITNESS: Probably not.	15	later as well working with a proctor.	
16	BY MS. SUTHERLAND:	16	But there's no credentialing	
17	Q. And do you know how many surgeons	17	required for someone to be able to	
18	in the United States are trained in the	18	implant a TVT-O; so they may or may not	
19	surgical treatment of stress urinary	19	have had specific training.	
20	incontinence?	20	But you have to go back to the	
21	MR. GOSS: Objection. Form.	21	point of the labeling. The manufacturer	
22	MS. VERBEEK: Same objection.	22	owns that document. It is the key point	
23	THE WITNESS: I can tell you	23	of communication, the IFU, with the	
24	•	24	physician who's going to be using the	
25	approximately how many urogynecologists,	25		
25	gynecologists, and urologists there are	25	product. And, therefore, all necessary	
	Page 159			Page 161
1	in total. How many have actually, you	1	important information must be in there.	
2	know, practiced in the treatment of SUI,	2	For example, the groin and	
3	I don't have a specific number, but	3	thigh pain. The percentage is as high	
4	there are in the high 30 thousands, if I	4	as in the 20 percents, 20 percent or	
5		5		
	recall correctly, of ones who are listed		more for groin and thigh pain in some	
6	as active.	6	clinical studies. Doctors who are	
7	BY MS. SUTHERLAND:	7	implanting the TVT-O, if they've not	
8	Q. All right.	8	read the literature, they're not up to	
9	A. And practice.	9	date on the literature, would not know	
10	Q. And if I'm understanding the basis	10	that.	
11	of your opinion that frequency data from	11	That's the reason that type of	
12	adequately reported clinical studies is not	12	information should be in the IFU.	
13	well known to the user of the TVT-O, that	13	MS. SUTHERLAND: All right.	
14	basis is your review of approximately ten or	14	I'm going to move to strike that entire	
15	less depositions?	15	answer.	
16	MR. GOSS: Objection. Form.	16	Would you read my question	
17	THE WITNESS: I'm saying that	17	back?	
18	there I'll take the counter argument,	18	(Record read by the	
19	so to speak, to your question that	19	reporter as follows:	
20	you're asking how many surgeons there	20	BY MS. SUTHERLAND:	
21	are that may practice in SUI.	21	Q. Is that true?	
22	First of all, the labeling is	22	A. Not as you've asked the question.	
23	the cornerstone of risk management, and	23	No, that's not true.	
<sub>1</sub> ∠J				
	the nurnose is to provide all	14		
24	the purpose is to provide all	24 25	Q. Are you assuming that the 30,000 or	
	the purpose is to provide all information necessary for safe and	2 <del>4</del> 25	so surgeons, and it might be less, that are	

Page 162 Page 164 1 actually trained in the surgical treatment 1 I've not seen any evidence that Ethicon has 2 of stress urinary incontinence do not know ever done this survey in order to exclude 3 3 frequency data of adverse events? incorporating that information. 4 MR. GOSS: Objection. Form. 4 O. I'm asking what you have done. 5 5 A. I have not done a survey, but short BY MS. SUTHERLAND: 6 of Ethicon, who has a responsibility for the 6 Q. Are you making that assumption? 7 A. I'm not making an assumption. I'm 7 labeling, never having done such a survey, 8 stating that it's really irrelevant as to 8 then the information needs to be included. 9 what goes in the labeling. There are 9 One would be making a large 10 standards. There are regulations, and 10 assumption to think that every physician of 11 there's a global standard for what's 11 those 30-plus thousand has read all of the 12 supposed to go into the labeling. 12 literature that's available. And going to the second point here, O. Aren't you making an assumption 13 13 information when needed and deciding between that they haven't? 14 14 the use of the device and an alternative A. But that's the point. The 15 15 16 procedure or approach, having that 16 labeling -information is critical to understanding 17 17 Q. Give me a ves or no, please. Are 18 what the risks are for one product versus 18 you making an assumption that they haven't another, and without that information, the 19 19 read the literature? 20 labeling does not serve its purpose which is 20 MR. GOSS: No, no, no. We're to provide, again, all the information 21 not going to start interrupting her by 21 22 necessary for safe and effective use of the 22 telling her what she's going to do and 23 product. 23 what she's not going to do. You can ask 24 Q. And I appreciate that, but my 24 your question. She can answer the 25 question is the Blue Book that you're 25 question. You can object nonresponsive. Page 163 Page 165 relying on for your opinion that frequency 1 But let's not interrupt each other. 1 2 2 data needs to be in the IFU says, "You BY MS. SUTHERLAND: 3 provide frequency data when that data is not 3 Q. Aren't you making an assumption well known to the device user." And I'm 4 4 that --5 5 trying to get what have you done to MR. GOSS: Are you finished? 6 determine that the frequency data is not 6 Were you finished with your answer? 7 7 THE WITNESS: I don't remember well known to the device users of TVT-O? 8 8 MR. GOSS: Objection. Form. my point. 9 BY MS. SUTHERLAND: 9 BY MS. SUTHERLAND: 10 Q. And you haven't done a survey of 10 Q. I'll start over. Aren't you making physicians; correct? an assumption that surgeons trained in the 11 11 12 A. No. Nor did the company. 12 surgical treatment of stress urinary 13 Q. You've read approximately ten 13 incontinence have not read the medical depositions of surgeons for the TVT-O; literature and, therefore, are not versed in 14 14 15 correct? 15 frequency data? A. What I am saying I am not making 16 A. Yes. 16 any assumption. What I'm saving is that I'm 17 O. All right. What have you done 17 18 otherwise, if anything, to be able to opine 18 doing -- I'm recommending -- I'm opining that frequency data from adequately reported that one ensures that the information is 19 19 20 clinical studies is not well known to the 20 available, which is what a reasonably 21 TVT-O device user? 21 prudent medical device manufacturer would do 22 A. I have looked up and evaluated the 22 to ensure that the information is available total numbers of physicians that have the 23 23 because one cannot know if every surgeon who potential credentials to implant this 24 24 might use this product has read the 25 device, and one has to -- Ethicon didn't --25 literature.

1		Page 166			Page 168
1	Then the manufacturer who owns the	_	1	A. Well, adverse events can result	
2	label must ensure that the necessary		2	from that.	
3	information for safe and effective use of		3	Q. Well, for instance, like erosion	
4	the product is provided.		4	could result from one or the other of the	
5	Q. All right. Let me ask it one more		5	things that you said. But I'm asking	
6	time. What, if anything, have you done to		6	specifically about an adverse event that you	
7	determine that surgeons trained in the		7	think ought to be listed in the IFU with	
8	surgical treatment of stress urinary		8	frequency data.	
9	incontinence do not know the frequency data		9	Is there a particular Ethicon	
10	from adequately reported clinical studies?		10	document that you're thinking of that	
11	MR. GOSS: Objection. Form.		11	supports your opinion that users of the	
12	THE WITNESS: I've already		12	TVT-O device didn't know about the frequenc	v l
13	indicated that I've read depositions of		13	data from adequately reported clinical	<b>'</b>
14	different physicians. I've read		14	studies?	
15	obviously lots of internal		15	MR. GOSS: Objection. Form.	
16	documentation, scientific literature,		16	THE WITNESS: As you've asked	
17	and I've evaluated, I've assessed the		17	the question, I can't think of a	
18	total number of potential physicians in		18	specific document that says they don't	
19	this country who could be using this		19	know the frequency of this, but I can	
20	product.		20	think of many documents that say	
21	BY MS. SUTHERLAND:		21	doctors that this information has not	
22	Q. Okay.		22	been made available to doctors.	
23	A. And based on that and based on		23	BY MS. SUTHERLAND:	
24	what should be included in the label for		24	Q. Okay. I'm going to move to strike	
25	safe and effective use of the product, I		25	after your first sentence.	
	bare and effective use of the producty I			arter your mot benteries	
		Page 167			Page 169
1	arrived at my opinions.	. ago 107	1	Now, you can set aside that IFU and	. 490 200
2	Q. Is there an internal Ethicon		2	pull out your report from this case, the	
3	document that says that frequency data for a		3	2015, and turn to pages 78 and 79, if you	
4	particular adverse event is not well known		4	would. I'll tell you where I'm going with	
5	to device users?		5	this.	
6	MR. GOSS: Objection. Form.		6	I want to get from you exactly what	
7	THE WITNESS: Ask that question		7	you intend to tell a jury ought to be listed	
8	again, please.				
. ()			8	under the adverse reactions section of the	
			8	under the adverse reactions section of the TVT-O IFU in 2010.	
9	BY MS. SUTHERLAND:		9	TVT-O IFU in 2010.	
9 10	BY MS. SUTHERLAND: Q. Sure. I thought you said as part		9 10	TVT-O IFU in 2010.  Does that make sense?	
9 10 11	BY MS. SUTHERLAND: Q. Sure. I thought you said as part of your bases for your opinion that you're		9 10 11	TVT-O IFU in 2010.  Does that make sense?  A. Yes, it does.	
9 10 11 12	BY MS. SUTHERLAND: Q. Sure. I thought you said as part of your bases for your opinion that you're relying on internal Ethicon documents.		9 10 11 12	TVT-O IFU in 2010.  Does that make sense?  A. Yes, it does.  Q. All right. So I've read through	
9 10 11 12 13	BY MS. SUTHERLAND: Q. Sure. I thought you said as part of your bases for your opinion that you're relying on internal Ethicon documents. A. Right.		9 10 11 12 13	TVT-O IFU in 2010.  Does that make sense?  A. Yes, it does.  Q. All right. So I've read through your report and saw the list on page 78 and	
9 10 11 12 13 14	BY MS. SUTHERLAND: Q. Sure. I thought you said as part of your bases for your opinion that you're relying on internal Ethicon documents. A. Right. Q. So is there such a document from		9 10 11 12 13 14	TVT-O IFU in 2010.  Does that make sense?  A. Yes, it does.  Q. All right. So I've read through your report and saw the list on page 78 and 79, and I want to ask you is this listing on	
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	Page 170			Page 172
1	don't want to play any tricks on you.	1	A. Yes.	
2	Groin pain and leg pain is not	2	Q. Okay. And now tell me specifically	
3	listed in those bullet points. Should it	3	on the leg pain, groin pain issue what	
4	be, according to your opinion?	4	exactly you would add to this list	
5	A. Yes. And let's see. I do address	5	language-wise?	
6	that on page 81.	6	A. "Leg, groin, inner thigh pain that	
	Q. Yeah. And that's why	7		
7	A. And 82 and 83.		may be chronic may require analgesics for	
8		8	pain management and may require mesh	
9	Q I'm asking should those be	9	excision	- 1
10	additional two additional bullet points	10	Q. Okay.	
11	that we add to these bullet points on 78 and	11	A and complete mesh removal may	- 1
12	79?	12	not be possible and leg movement may be	- 1
13	A. Yes. And that's indicated on	13	affected."	- 1
14	page 83 where I note that "By no later than	14	Q. So that whole	- 1
15	2007, Ethicon had the responsibility to	15	A. And that the complication this	- 1
16	update the IFU to advise physicians that	16	goes back to what we were talking about	- 1
17	leg, groin, inner thigh pain may be chronic,	17	earlier about the frequency, that the	
18	may require analgesics for pain management	18	likelihood of this complication is	- 1
19	and may require mesh excision and complete	19	significantly higher for TVT-O versus TVT.	- 1
20	mesh removal, may not be possible. As well,	20	Q. And so that, what all you just	- 1
21	leg movement may be affected and, moreover,	21	said, ought to be in one bullet point under	- 1
22	the likelihood of this complication is	22	adverse reactions?	- 1
23	significantly higher for TVT-O implantation	23	A. Some of it might be in the warnings	- 1
24	versus TVT."	24	like the TVT this is the complication	- 1
25	Q. So let me be sure I've got a	25	rate is higher for TVT-O than for TVT, for	- 1
	Q. So let me be said I to got a		rate is riighter for 111 o than for 111, 10.	
	Page 171			Page 173
1	Page 171 complete listing here. As I understand	1	example.	Page 173
1 2	complete listing here. As I understand	1 2	example. O. Okay. Now	Page 173
2	complete listing here. As I understand it well, first of all, let me ask you.	2	Q. Okay. Now	Page 173
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Page 174 Page 176 79 in the order that you would place it clinical studies, which there is data 1 1 available like the groin and thigh pain. 2 according to clinical significance based on 2 There are studies that report in the 20 3 severity and frequency? percents ranges for groin and thigh pain in 4 A. No. 5 certain studies. 5 Q. How would you order this list? 6 Q. Okay. 6 A. I haven't done that evaluation. I A. And so for things of nature, again, 7 7 would do -- I would go through the process 8 yes, because that then helps a clinician, 8 that I talked about earlier is looking at the surgeon in this case, to understand when 9 9 doing an evaluation of the available data 10 he's deciding what type -- what the 10 through commercial experience, through what 11 frequency of dyspareunia is, for example, 11 the company knew at the time of launch of and whether or not it's short term or long 12 12 the product, is documented in the 13 term. documentation from the company, through the 13 That type of information is 14 14 scientific medical literature, through 15 critical for the surgeon to know as he works the -- the clinical -- any clinical 15 with the patient to make a decision is what 16 information that may be available for 16 17 the best treatment is for this patient. similar products if not the company's own 17 18 Q. Okay. I'm going to move to strike 18 product, looking at all of that and then 19 everything after "yes." evaluating what the percentages of 19 20 Actually, would you read my 20 occurrence are, what the range of occurrence 21 question back? 21 is because different studies will report 22 (Record read by the 22 different ranges, look at the frequency, 23 reporter as follows: 23 look at the severity, look at the Is it your opinion, for instance, that -- let's 24 permanency, the chronicity, and then as part 24 just assume, if you will for now, that like the of the project team, evaluate that and first three are listed in the correct order 25 25 Page 175 Page 177 determine what are the most important ones, 1 according to the Blue Book Memo. All right? Is it 1 2 2 what clinicals, which ones should be your opinion that they also need to have some sort 3 presented as most clinically significant for 3 of frequency rate or percentage out beside them?") BY MS. SUTHERLAND: this particular device and present them in 4 4 Q. Okay. And I think your answer to 5 that way. 5 6 6 that was yes; correct? So it's an evaluation that needs to 7 7 A. I think I also said that if that be undertaken in that type of a framework. 8 8 Q. Okay. I'm going to move to strike information is available from clinical 9 everything after "I have not done that 9 studies. 10 evaluation." 10 Q. Okay. Is that information Would it be fair to say, though, available from clinical studies for all of 11 11 your bullet points on pages 78 to 79? that at least as you sit here today, you're 12 12 not intending to tell a jury the order that A. One would have to do -- there is 13 13 your bullet points ought to be listed in? information on all of these in the 14 14 15 A. That's correct. 15 literature, yes, but that -- one would have Q. Okay. Now -- oh, one more thing on to do an assessment of the literature and 16 16 look at ranges that were reported and make the bullet points. Is it your opinion, for 17 17 18 instance, that -- let's just assume, if you 18 determinations so that you could say, you will for now, that like the first three are know, ideally this information comes from 19 19 listed in the correct order according to the 20 the company having done its own clinical 20 Blue Book Memo. All right? Is it your 21 21 studies. 22 opinion that they also need to have some 22 Q. Have you done the determination as sort of frequency rate or percentage out to what the frequency rates ought to be for 23 23

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beside them?

A. If that data is available through

all of your bullet points?

A. I actually have in some of my

Peggy Pence, Ph.D. Page 178 Page 180 they respond to implantation of mesh and the 1 reports some that are indicated in some of 1 2 the systematic reviews that have been done. Ethicon documentation reflects that there 3 I've not done and I have looked at that in 3 are certain factors related to individual 4 4 terms of looking at each one of these and patients' medical status that might impact 5 5 evaluating the entirety of the literature how well they would respond to implantation and making a determination for each of these of the device or whether or not it might 6 6 7 as to what I would include or whether or not 7 increase their risk for complications, in 8 8 other words. So those factors would be it needs to be included for every one. 9 I have not done that determination, 9 appropriately included in the warnings and 10 but it certainly, for the more clinically 10 precautions section. 11 significant ones, that's appropriate to do. 11 And then the other one is that 12 Q. Okay. And tell me which ones are 12 while the -- with regard to degradation and 13 the more clinically significant ones that 13 that the mesh may degrade and that with you're talking about there? degradation, that that may impact the safety 14 14 A. Certainly the groin and leg, inner and effectiveness, whereas I -- if I recall 15 15 thigh pain, the effect on walking, the correctly, the IFU states that the product 16 16 erosion, the rates of erosion, the does not degrade. 17 17 18 shrinkage, the urinary problems, the ones 18 Yes, it says under the action that occur most frequently. section on the last page, "The material is 19 19 20 But, again, in order to do that and 20 not absorbed nor is it subject to 21 give the right percentages, one would go 21 degradation or weakening by the action of tissue enzymes." 22 through the process that I have already 22 23 described. 23 Q. Okay. Let me go back to your first 24 Q. Okay. Now, let me turn -- well, 24 point on the patient factors. What specific patient factors are you talking about there 25 let me make sure. Have you given me your 25 Page 179 Page 181 opinions that you're going to offer to a 1 for inclusion under warnings? 1 2 2 jury as to what ought to be under the A. For example, if there's any 3 adverse reaction section of the TVT-O IFU? 3 potential scarring already there as a result 4 A. Yes, in terms of missing data, yes. 4 of prior surgeries, information of that 5 Q. Right. Okay. Now, I'm going to 5 nature. 6 turn to your warnings and precautions. 6 Q. Okay. Anything else under warnings 7 7

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- A. Missing adverse reactions, I should say.
- Q. Yeah. So let me turn to the warnings, and am I correct that the warnings information that you think should be in the TVT-O IFU as of 2010, that is set out on pages 79 and 80 and top of 81 and also includes the leg and groin pain that you and I already talked about?
  - A. That's correct.
- O. All right. Is there anything else that you intend to opine ought to be in the warnings section of the TVT-O IFU as of 2010?
- 21 A. There are -- there are two points 22 that I would add.
- 23 Q. Okay.

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- 24 A. One is that factors that --
- patient-related factors that may affect how 25

- that you're going to opine about ought to be in the TVT-O IFU as of 2010?
- 9 A. With regard to the I think -- or I 10 should say with regard to "Chronic pain may result from foreign body reaction and/or 11 scarring and contraction," the information 12 that's provided there, if asked, I would 13 also opine that that scarring and 14 15 contraction in addition to pain may also result in vaginal tightening and distortion 16 of the vagina. 17
  - Q. Okay.
- A. And as regards the dyspareunia, 19 20 occurring and being persistent --
  - Q. I'm sorry. Where are you?
- 22 A. Also on top of page 80.
- Q. Oh, "De novo dyspareunia may occur 23
- 24 and be persistent"?
- 25 A. Yes. That -- that sexual function

	Page 1	2		Page 184
1	may be affected for a lifetime. There's the	1	on Ethicon's professional education, as I've	
2	potential that sexual dysfunction	2	described that term to you?	
3	Q. You're just adding length	3	A. As I sit here today, no.	
4	A. Between that and the vaginal	4	Q. Okay. Do you agree that doctors	
5	tightening and narrowing, that between both	5	can get information about surgical treatment	
6	of those, that there's the potential that a	6	of SUI including the use of TVT-O from	
7	patient would not be able to have sexual	7	medical school training?	
8	intercourse.	8	A. Yes.	
9	Q. Okay. Anything else?	9	Q. All right. Depending on	
10	A. As I sit here today	10	MR. GOSS: Objection. Form.	
	•			
11	Q. I know you're trying hard. You've	11	MS. VERBEEK: Objection.	
12	got to come up with one more. That's the	12	THE WITNESS: Depending on the	
13	best you've got right now?	13	medical school and what the training	
14	A. Yes.	14	program is and how extensive their	
15	Q. All right. Let me switch gears on	15	involvement is.	
16	you for a minute, and I want to talk to you	16	BY MS. SUTHERLAND:	
17	about sources of information other than the	17	Q. Do you know if the TVT-O procedure	
18	IFU for doctors. Okay?	18	is taught in medical school?	
19	A. I understand.	19	A. I don't know that it would be	
20	Q. Would you agree that professional	20	taught in medical school so much as it might	
21	education could be a source of information	21	be taught in residencies.	
22	with respect to the risks associated with	22	Q. Okay.	
23	the TVT-O?	23	A. But I haven't I can't say that	
24	A. Yes. It's not the primary source.	24	specifically. I've not studied it.	
25	It is a source.	25	Q. Would medical literature be another	
				D 105
	Page 1	3 1		Page 185
- 1			source of information for doctors about	9
1	Q. Okay. And while I'm on that, I did	1	source of information for doctors about	
2	Q. Okay. And while I'm on that, I did not see any opinion of yours in your report	1 2	risks associated with surgical treatment of	
2	Q. Okay. And while I'm on that, I did not see any opinion of yours in your report as to professional education.	1 2 3	risks associated with surgical treatment of SUI including TVT-O?	
2 3 4	Q. Okay. And while I'm on that, I did not see any opinion of yours in your report as to professional education.  Do you intend to offer any opinions	1 2 3 4	risks associated with surgical treatment of SUI including TVT-O?  A. Yes.	
2 3 4 5	Q. Okay. And while I'm on that, I did not see any opinion of yours in your report as to professional education.  Do you intend to offer any opinions in the Jennifer Ramirez case about	1 2 3 4 5	risks associated with surgical treatment of SUI including TVT-O? A. Yes. Q. Would talking to colleagues be	
2 3 4 5 6	Q. Okay. And while I'm on that, I did not see any opinion of yours in your report as to professional education.  Do you intend to offer any opinions in the Jennifer Ramirez case about professional education?	1 2 3 4 5 6	risks associated with surgical treatment of SUI including TVT-O?  A. Yes. Q. Would talking to colleagues be another source of information for doctors?	
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	Page 186			Page 188
1	know the complications with their own	1	THE WITNESS: Dr. Reyes did.	
2	patients because many times patients who	2	BY MS. SUTHERLAND:	
3	have complications don't return to the	3	Q. Are you aware that some doctors do	
4	doctor who did the implantation, such as in	4	not read IFUs before implanting surgical	
5	the case with Ms. Ramirez.	5	mesh?	
6	She didn't return to Dr. Reyes to	6	MS. VERBEEK: Objection. Form.	
7	do her revision. She went to other	7	MR. GOSS: Objection. Form.	
8	physicians for her revisions. And so that	8	THE WITNESS: There may be some	
9	happens, and when that happens, doctors are	9	doctors who don't. But without asking	
10	not aware that their patients have had	10	every doctor, I can't say that. And	
11	complications.	11	irregardless, whether that happens or	
12	(Mr. Goss exits the proceeding.)	12	not, it's the manufacturer's	
13	MS. SUTHERLAND: I'm going to	13	responsibility to be sure that the IFU	
14	move to strike everything after "yes."	14	is contains all the necessary	
15	BY MS. SUTHERLAND:	15	information for safe and effective use	
16	Q. Do you agree that should I wait	16	of the product, and it's truthful and	
17	for him to come back?	17	accurate and not misleading.	
18	A. Probably.	18	BY MS. SUTHERLAND:	
19	MS. SUTHERLAND: Let's go off.	19	Q. Okay. I'm going to move to strike	
20	THE VIDEOGRAPHER: Going off	20	everything after your first phrase and	
21	the record. The time is approximately	21	response.	
22	1:54 p.m.	22	In your opinion, how often should a	
23	(Recess taken from	23	doctor read a device IFU?	
24	1:54 p.m. to 1:54 p.m.)	24	MR. GOSS: Objection. Form,	
25	THE VIDEOGRAPHER: Back on the	25	foundation.	
	Page 187			Page 189
1	Page 187 record. The time is approximately	1	MS. VERBEEK: Same objection.	Page 189
1 2	record. The time is approximately	1 2	MS. VERBEEK: Same objection. BY MS. SUTHERLAND:	Page 189
2	record. The time is approximately 1:54 p.m.	2	BY MS. SUTHERLAND:	Page 189
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	record. The time is approximately 1:54 p.m. BY MS. SUTHERLAND: Q. All right. Dr. Pence, do you agree that doctors who implanted the TVT-O may have learned of the risks of that device through means other than the IFU? MR. GOSS: Objection. Form. MS. VERBEEK: Same objection. THE WITNESS: Some doctors may have learned of some of the risks through other means, but that, again, would be an assumption. It's not the primary means of communicating risks to the doctor. The primary means is the IFU. So one can't rely on a doctor having learned about the risks on based on other sources. BY MS. SUTHERLAND: Q. Okay. I'll move to strike everything after your first phrase. Are you aware that some doctors don't read the IFU before implanting	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	BY MS. SUTHERLAND: Q. Or do you have an opinion on that? You may not. I don't know. A. Dr. Reyes testified he went back to it many times and reviewed it. It definitely should be reviewed any time there's new information that is important to the doctor. Q. How would a doctor know there's new information if he doesn't review it?  MR. GOSS: Objection. Form.  THE WITNESS: Well, if there's an IFU in every mesh package, and if the manufacturer wants to ensure that the physician knows that there is an update that's important for him or her to know, then a red card, for example, there are different means where that can be attached with a new IFU that says, "Please refer to section adverse reactions and warnings when new information has been added for the safe	Page 189

letter can be sent out saying, "We've updated the IFU. Here's a copy. This is the information that's changed. We feel its important for you to know that."  BY MS. SUTHERLAND:  Read of the We're aware of, not from reading the IFU, but from their medical school or residency that."  Read of the We're aware of, not from reading the IFU, but from their medical school or residency that."  Read of the We're aware of, not from reading the IFU, but from their medical school or residency that."  Read of the We're aware of, not from reading the IFU, but from their medical school or residency that."  Read of the We're aware of, not from reading the IFU, but from their medical school or residency that."  Read of the We're aware of, not from reading the IFU, but from their medical as univery.  Read of the We're aware of, not from reading the IFU, but from their medical as the out of survey, no.  Read of the We're aware of, not from reading the IFU, but from their medical as univery.  Read of the We're aware of, not from reading the IFU, but from their medical as chool or residency that."  Read of the We're aware of, not from reading the IFU, but from their medical as chool or residency that."  Read of the We're aware of, not from reading the IFU, but from their medical as considered as univery.  Read of the We're aware of, not from reading the IFU, but from their medical as univery, no.  Read of the We're aware of, not from reading the IFU, but from their medical as univery.  Read of the We're aware of, not from reading the IFU, but from their medical as univery.  Read of the We're aware of, not from reading the IFU, but from participating in repart to remove the amount of the we're aware of not from reading the IFU, but from participating in professional education?  Reading the IFU, but from participating in professional education?  Reading the IFU, but from participating in professional education?  Reading the IFU, but from participating in professional education?  Reading the IFU, but from participating in professional ed					
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			,		
		Page 194			Page 196
1	trained in the surgical treatment of SUI to		1	MR. GOSS: Objection. Form.	
2	determine what risks of the TVT-O they		2	BY MS. SUTHERLAND:	
3	understood, not from reading the IFU, but		3	Q. All right. And there are over 60	
4	from their own clinical experience		4	RCTs or randomized control trials for TVT-O?	
	·		5		
5	implanting the TVT-O?			MR. GOSS: Objection. Form.	
6	MR. GOSS: Objection. Form.		6	THE WITNESS: Yes, not	
7	MS. VERBEEK: Same objection.		7	necessarily conducted by Ethicon.	
8	THE WITNESS: Again, the		8	BY MS. SUTHERLAND:	
9	whether or not I the answer to any		9	Q. And is it your understanding that	
10	such survey would not impact my opinion		10	there are over a thousand studies I'm not	
11	as to what should be in the IFU, and		11	saying RCTs but over a thousand studies on	
12	I've not conducted such a survey. But		12	TVT?	
13	also to that point, their own clinical		13	MR. GOSS: Objection. Form.	
14	experience may not be representative of		14	THE WITNESS: I have seen that	
15	the risks of the points I mentioned a		15	number, yes.	
16	little while ago that patients who		16	BY MS. SUTHERLAND:	
17	experience serious complications, and		17	Q. Okay. Have you looked at the	
18	it's reflected in the literature, do not		18	patient brochure for the TVT-O in this case?	
19	often return to the implanting		19	A. My understanding that Ms. Ramirez,	
20	clinician.		20	if I'm recalling correctly, does not recall	
21	So the implanting surgeon would		21	having received a brochure, although I	
22	not know about those risks. So their		22	believe, to the best of my recollection as I	
23	experience may not be a very accurate		23	sit here today, Dr. Reyes thought he would	
24	reflection of what the complication rate		23 24	have given her one, but she did not	
25	is, and it would be foolhardy to rely on		25	recall if I'm recalling correctly, she	
23	is, and it would be roomardy to rely on		23	recall If I'll recalling correctly, she	
		Page 195			Page 197
1	their experience only	Page 195	1	did not recall having received one	Page 197
1 2	their experience only.	Page 195	1 2	did not recall having received one.	Page 197
2	BY MS. SUTHERLAND:	Page 195	2	Q. All right. I thought I was done	Page 197
2	BY MS. SUTHERLAND: Q. All right. I'm going to move to	Page 195	2 3	Q. All right. I thought I was done with these questions. A couple more.	Page 197
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2 3 4 5	BY MS. SUTHERLAND: Q. All right. I'm going to move to strike. Is the answer to my question that	Page 195	2 3 4 5	Q. All right. I thought I was done with these questions. A couple more. Have you conducted a study or survey to determine whether the inclusion,	Page 197
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		1			
		Page 198			Page 200
1	the inclusion of your listed adverse		1	have known about.	
2	reactions on pages 78 to 79 of your report		2	But remember, the public health	
3	would have changed their decision to implant		3	notification was based on an evaluation	
4	TVT-O?		4	of the MAUDE database. And so this was	
5	MR. GOSS: Objection. Form.		5	information coming from one of the	
6	THE WITNESS: I've not done a		6	sources of information that was	
7	survey.		7	available for identifying potential	
8	MS. VERBEEK: Objection.		8	risks with the TVT-O and other sling	
9	BY MS. SUTHERLAND:		9	polypropylene slings.	
10	Q. Okay. In your report, I think it's		10	BY MS. SUTHERLAND:	
11	on page 60, you list out what was listed in		11	Q. They look at literature too; right?	
12	the FDA's public health notice from 2008, if		12	A. That was in 2011. They did	
13	you want to turn to that.		13	you're talking about now about the 2008	
14	A. Which page?		14	public health notification.	
15	Q. Page 60.		15	Q. Yeah. Are you saying FDA had not	
16	A. Page 60.		16	reviewed literature for the risks associated	
17	Q. And I'm actually just curious about		17	with pelvic mesh	
18	this. Is it your opinion that the		18	A. The 2008 public health	
19	complications that the FDA listed in its		19	notification	
20	2008 PHN		20	(Simultaneous discussion	
21	A. You're on page 60?		21	interrupted by the reporter.)	
22	Q. Yeah. Are you not there?		22	MR. GOSS: She's going to have	
23	A. My page 60 is Section 7 "TVT		23	a long enough day as it is. Let's try	
24	Classic and TVT Obturator: Known/Knowable		24	to not step on each other.	
25	Risks."		25	THE WITNESS: I'm sorry. The	
		Page 199			Page 201
1	Q. Uh-huh.	Page 199	1	2008 public health notification, to the	Page 201
2	A. And you said something about the		2	best of my recollection, and I can just	
3	Q. And then you've got yeah your		3	verify that, was based on a review of	
4	paragraph talks about		4	the MAUDE database.	
5	A. Oh, you're talking about I see.			It was in 2011 that the FDA	
_			ר	II WAS III ZULL IIIAI IIIE EDA	
			5 6		
6	I have a section on FDA. I thought you		6	conducted an evaluation of the	
6 7	I have a section on FDA. I thought you might be in that section. I'm sorry.		6 7	conducted an evaluation of the scientific and medical literature from	
6 7 8	I have a section on FDA. I thought you might be in that section. I'm sorry. Q. No, no, no. Let me make sure I		6 7 8	conducted an evaluation of the scientific and medical literature from 1996 through 2011. So what I'm saying	
6 7 8 9	I have a section on FDA. I thought you might be in that section. I'm sorry. Q. No, no, no. Let me make sure I thought I had this right. Are the bullet		6 7 8 9	conducted an evaluation of the scientific and medical literature from 1996 through 2011. So what I'm saying is that the 2008 public health	
6 7 8 9 10	I have a section on FDA. I thought you might be in that section. I'm sorry.  Q. No, no, no. Let me make sure I thought I had this right. Are the bullet points that you've listed there on pages 60		6 7 8 9 10	conducted an evaluation of the scientific and medical literature from 1996 through 2011. So what I'm saying is that the 2008 public health notification was based only on one	
6 7 8 9 10 11	I have a section on FDA. I thought you might be in that section. I'm sorry.  Q. No, no, no. Let me make sure I thought I had this right. Are the bullet points that you've listed there on pages 60 to 61 the adverse reactions listed by the		6 7 8 9 10 11	conducted an evaluation of the scientific and medical literature from 1996 through 2011. So what I'm saying is that the 2008 public health notification was based only on one source of information, whereas Ethicon	
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		Page 202			Page 204
1	those. The company did as well as the	•	1	MS. VERBEEK: Form.	
2	scientific and medical literature as		2	THE WITNESS: what every	
3	well as the information from the experts		3	surgeon what was well known to every	
4	and with their summit meetings, with the		4	surgeon. That's the reason the	
	<del>_</del> :		5	5	
5	experts that they met with.			information I keep going back to the	
6	They had that's why the		6	purpose of the IFU and the reason that	
7	manufacturer is the greatest repository		7	information has to be in the IFU. The	
8	of the information related to their own		8	company was well aware of these, as is	
9	product. So this information definitely		9	noted here in my report.	
10	should have been in there, but there was		10	There are a number of senior	
11	more beyond that that should have be		11	employees, senior executives at Ethicon	
12	included.		12	that have testified that all of these	
13	BY MS. SUTHERLAND:		13	all of this information was known to	
14	Q. I'm going to respectfully move to		14	Ethicon at the time of launch. And in	
15	strike that answer and the previous answer		15	my own analysis, which I presented in my	
16	after "No, it was not adequate" because I		16	report, I did the analysis as to what	
17	think my question to you was: Was this		17	was known at time of launch based on	
18	listing by FDA in 2008 of adverse reactions		18	MAUDE database, based on internal	
19	adequate had it been in an IFU for a pelvic		19	documentation, deposition testimony,	
20	mesh device in 2008?		20	based on the scientific literature, and	
21			21		
	A. No, for the reasons I explained.			I was able to make that analysis of	
22	Q. All right. Was mesh erosion a		22	everything that should have been in the	
23	well-known complication in 2008?		23	IFU at time of launch back in, 2000	
24	A. Yes.		24	end of 2003, 2004 and was missing.	
25	Q. All right. Was infection a		25	BY MS. SUTHERLAND:	
$\vdash$					
		D 202			D 205
1	well known complication in 20002	Page 203	1	O. The gains to make to stuike	Page 205
1	well-known complication in 2008?	Page 203	1	Q. I'm going to move to strike	Page 205
2	A. Yes.	Page 203	2	everything after "No, I can't tell you what	Page 205
2	<ul><li>A. Yes.</li><li>Q. Was pain a well-known complication</li></ul>	Page 203	2	everything after "No, I can't tell you what was known by surgeons."	Page 205
2 3 4	A. Yes. Q. Was pain a well-known complication in 2008?	Page 203	2 3 4	everything after "No, I can't tell you what was known by surgeons."  Is it your opinion that the adverse	Page 205
2 3 4 5	<ul><li>A. Yes.</li><li>Q. Was pain a well-known complication</li><li>in 2008?</li><li>A. Yes. You're talking about well</li></ul>	Page 203	2 3 4 5	everything after "No, I can't tell you what was known by surgeons."  Is it your opinion that the adverse reactions that were listed in the FDA's 2008	Page 205
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Page 206 Page 208 approval of counsel, back on the record. was based on data from 2005 to 2007, if 1 1 2 The time is approximately 2:27 p.m. 2 I recall correctly. 3 3 BY MS. SUTHERLAND: BY MS. SUTHERLAND: 4 O. Dr. Pence, I had marked the 2008 4 O. And while we're on that, let me ask 5 5 you something while you're on page 117 of PHN as Exhibit Number 11. 6 6 your report. Were you able to duplicate a Do you have that in front of you? 7 A. I do. 7 search of the MAUDE database and come up 8 8 with the 1371 total number of MDRs like the (Exhibit Number 11 was 9 marked for identification.) 9 FDA did? 10 BY MS. SUTHERLAND: 10 A. I didn't look at all nine 11 Q. All right. And now, am I correct 11 manufacturers. I have shown and I show on that that PHN sets out certain complications 12 12 my report for TVT and TVT-O what the numbers 13 associated with pelvic mesh? 13 of reports of these particular events are Do you see that? and how they are representative in the order 14 14 of frequency of the adverse reactions for 15 A. Yes, I do. 15 Q. All right. And now, is it your those two devices are representative of the 16 16 understanding or is it your opinion that the nine manufacturers' events that were -- I 17 17 18 complications that are listed in that 18 believe it was nine manufacturers, if I paragraph starting "The most frequent" are 19 19 recall correctly as I sit here today, that 20 actually listed in the appropriate order 20 were included in FDA's assessment. 21 under the Blue Book Memo? 21 Q. Okay. I don't think you answered 22 MR. GOSS: Objection, Form. 22 my question. 23 THE WITNESS: Yes. And I was 23 A. I think I understand your question. 24 just going to make that point that you 24 I think I did. I think I said I haven't 25 can see that FDA lists the most frequent looked at all nine manufacturers. 25 Page 207 Page 209 complications, and that's what they 1 Q. So you have not attempted to 1 2 2 duplicate FDA's search to come up with the relied on, and I wanted to just verify that in the 2008 PHN, it did note that 3 3 1371 that FDA came up with that's listed in 4 those were the most frequent. 4 the PHN; correct? 5 It's also reflected -- if you 5 A. No, not that specifically. I 6 look in my report on page -- let me find 6 relied on FDA's evaluation for that. But 7 it again. On page 117, I have a tabular 7 what I did do as relevant to my report is look into TVT and TVT-O to see how the data 8 8 presentation of the number percent of 9 adverse events for SUI reported to MAUDE 9 for TVT and TVT-O compared to FDA's data 10 from 2008 to 2010, which was the data 10 across the multiple manufacturers. And to 11 that was reflected in the 2000 -- FDA's that point, in one of the reports, FDA noted 11 12 2011 safety communication. 12 that the -- there did not seem to be a 13 And you can see there that the 13 difference across the types of events that 14 numbers of reports of pain, erosion, and were reported across manufacturers. 14 15 so forth and you can see the order of 15 Q. Okay. Let me ask it again. Did frequency. And the total number of -you try to duplicate FDA's search that they 16 16 17 the total number of reports included for listed actually in their 2011 safety update 17 18 SUI in that MAUDE evaluation was 1371. 18 where they listed a total number of SUI So you can see the percent of those 1371 reports being 1,371? 19 19 20 reports that included pain. It was 20 A. No. I specifically looked at 21 34.9 percent. 21 certain manufacturers and certain products 22 So for the 2008 to 2010 data, 22 for those manufacturers. 23 you can see that the listing of the most Q. When you're looking at your 23 frequent complications is very similar Table 9.1 on page 117 --24 24 25 to the listing in the 2000/2008, which 25 A. Yes.

Q and you have there pain, 479 number of reports of pain.  Do you see where I am?  Q. And then you say that's  34. Yes.  Q. You are saying that 479 number of reports of pain is 34.9 percent.  To poy ou see where I am there?  A. Yes.  Q. All right. But let me ask you  If the interview of their 1,371?  A. Yes.  A. Yes.  Q. From the 2011 safety update?  A. WalDE database from 2008 to 2010, to the best of my recollection as I sit here today.  Let me just take a look and confirm.  Q. I din't recall the 2011 safety  Q. Q. Is that where the number of reports of pain, the number of reports of erosion.  Page 212  1 A. No. I took - I took FDA's numbers that they presented, which, again, if I recall, and I believe it's in my report, but if I recall correctly as I sit here today, that if I recall correctly as I sit here today, that is was across nine manufacturers, and I can look it up and verify that as well.  But I looked at TVT and TVT-O for that same time period, 2008 to 2010 - Q. Yeah.  A. Yes.  Q. All right. But the me ask you  12 table, I ve shown that that was 47.6 percent of the total number of reports of pain, and as you see in this table; the shown that that was 47.6 percent of the total number of reports of pain, and how does that was 47.6 percent of the total number of reports of pain, and how does that search of you run to find pain in the TVT/TVT-O reports, and how does that search of you run to find pain in the TVT/TVT-O reports, and how does that search of you run to find pain in the TVT/TVT-O reports, and how does that search of you run to find pain in the TVT/TVT-O reports, and how does that search of you run to find pain in the TVT/TVT-O reports, and how does that search of you run to find pain in the TVT/TVT-O reports, and how does that search of you run to find pain in the TVT/TVT-O reports, and how does that search of you run to find pain in the TVT/TVT-O reports, and how does that search of you run to find pain in the TVT/TVT-O reports of erosion.  1 A. You have to look at the executive and the		337		
2 mumber of reports of pain. 3 Do you see where I am? 4 A Yes. 5 Q. And then you say that's 6 34.9 percent. 7 Do you see where I am there? 8 A. Yes. 9 Q. You are saying that 479 number of reports of pain is 34.9 percent of the 1371? 11 A. Yes. 2 Q. All right. But let me ask you 12 diffectly from their report, yes. That was their finding. 13 A. I believe this information came 14 of their 1,371? 15 A. I believe this information came 16 directly from their report, yes. That was their finding. 18 Q. From the 2011 safety update? 19 A. Yes. Based on their review of the 20 MAUDE database from 2008 to 2010, to the 21 update setting out the number of reports of pain, the number of reports of the that that was 47.9 coming from? 1 A. You have to look at the executive summary and the information behind that that 5 FDA — 2 Q. Is that where the numbers are collection as 1 sit here today, that's owner that the same FDA's numbers, not mine. 2 Q. Okay. And then, if I'm understanding you correctly, if you turn to mine. 3 Q are you saying that, for instance, on the row of pain going across the mean facturers, and I can look at the exercutive and the pain of the pain in order to make your percentage valid? 2 Let me just take a look and confirm. 2 Q. I didn't recall the 2011 safety 20 and 20 an		Page 210		Page 212
Do you see where I am? A Yes. Q. And then you say that's Gardial correctly as I sik here today, this was across nine manufacturers, and I can look it up and verify that as well. Do you see where I am there? A. Yes. Q. You are saying that 479 number of reports of pain is 34.9 percent of the 1371? A Yes. Q. All right. But let me ask you to fit their 1,371? A. I believe this information came directly from their report, yes. That was their finding. Q. From the 2011 safety update? A. Yes. Based on their review of the Dest of my recollection as I sit here today. Let me just take a look and confirm. Q. I din't recall the 2011 safety dupdate setting out the number of reports of pain, the number of reports of erosion.  Page 211  A. You have to look at the executive summary and the information behind that that FDA — Q. Is that where the numbers are coming from? A. To the best of my recollection, that's correct. I probably have it footnoted. Let me — to the best of my recollection as I sit here today, that's where that — those are FDA's numbers, not mine. Q. C. Okay, And then, if I'm understanding you correctly, if you turn to find appa 123 of your report — A. Yes. Q. — are you saying that, for instance, on the row of pain going across there — Q. A Yes. Q. — that TVT, TVT-O reports are 228 of those reports out of those 479? A. That's correct. Q. — that TVT, TVT-O reports are 228 of those reports out of whose 479? A. That's correct, Q. All right. Did you do a search and A find 479 reports of pain out of which you  The page 123 of your report — A. To the best of my recollection, that's correct on the find of the	1	Q and you have there pain, 479	1	A. No. I took I took FDA's numbers
4. A. Yes.  Q. And then you say that's  6 34.9 percent.  Do you see where I am there?  A. Yes.  Q. You are saying that 479 number of reports of pain in 34.9 percent of their 1,371?  A. Yes.  Q. All right. But let me ask you  13 this. Did FDA find 479 reports of pain out this. Did FDA find 479 reports of pain out this. Did FDA find 479 reports of pain out this. Did FDA find 479 reports of pain out this. Did FDA find 479 reports of pain out this. Did FDA find 479 reports of pain out this. Did FDA find 479 reports of pain out this. Did FDA find 479 reports of pain out this. Did FDA find 479 reports of pain out this. Did FDA find 479 reports of pain out this. Did FDA find 479 reports of pain out the finding.  A. Yes.  Q. From the 2011 safety update?  MAUDE database from 2008 to 2010, to the best of my recollection as I sit here today.  Let me just take a look and confirm.  Q. I didn't recall the 2011 safety update setting out the number of reports of pain, in the number of reports of pain, in the number of reports of pain, and as you see in this table, I've shown that that was 47.6 percent of the total number of reports of pain, and as you see in this table, I've shown that that was 47.6 percent of the total number of reports of pain, and as you see in this table, I've shown that that was 47.6 percent of the total number of reports of pain, and as you see in this table, I've shown that that was 47.6 percent of the total number of reports of pain, and as you see in this table, I've shown that that was 47.6 percent of the total number of reports of pain, and as you see in this table, I've shown that that was 47.6 percent of the total number of reports of pain, and as you see in this table, I've shown that that was 47.6 percent of pain, and the was 47.6 percent of pain in order to make you run to find pain in the the total number of reports of pain in order to make you run to find pain in the the total number of reports of pain in order to make you gestent the company function of pain in order to make you gestent the	2	number of reports of pain.	2	that they presented, which, again, if I
5 Q. And then you say that's 34.9 percent. 7 Do you see where I am there? 8 A. Yes. 9 Q. You are saying that 479 number of 10 reports of pain is 34.9 percent of the 1371? 11 A. Yes. 12 Q. All right. But let me ask you 13 this. Did FDA find 479 reports of pain out 14 of their 1,371? 15 A. I believe this information came 16 directly from their report, yes. That was 17 their finding. 18 Q. From the 2011 safety update? 19 A. Yes. Based on their review of the 10 MAUDE database from 2008 to 2010, to the 11 best of my recollection as I sit here today. 12 Let me just take a look and confirm. 19 Q. I din't recall the 2011 safety 10 update setting out the number of reports of pain, and the pain in order to make your percentage valid? 1	3	Do you see where I am?	3	recall, and I believe it's in my report, but
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22 A. That's correct. 23 Q. All right. Did you do a search and 24 find 479 reports of pain out of which you 25 pain. And we FDA analyzed their own 26 MAUDE database and looking at their own 27 database, they came up with 479 reports				· · · · · · · · · · · · · · · ·
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24 find 479 reports of pain out of which you 24 database, they came up with 479 reports				
25 deross the fille manadetarers that they		·		· · · · · · · · · · · · · · · · · · ·
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Page 214 Page 216 manufacturers, then they're trying to be looked at, and from analyzing the very same 1 2 database for TVT and TVT-O only, we found comprehensive. Then it may be more. I 3 228 reports. 3 mean, there are more than nine 4 4 manufacturers; so they looked at nine O. Yeah. And I follow that. But my 5 5 question is: Did you do any kind of quality manufacturers. check with the searches you were running to 6 6 Q. And if I'm understanding this chart 7 find the TVT and TVT-O reports of pain to 7 that you have on 123, you are assuming in 8 ensure that you would have also found only 8 order to reach your percentage of all SUI 9 479 reports of pain like the FDA found? 9 mesh reports, that last column? 10 A. If I understand your question as 10 A. Yes. 11 you've asked it, the evaluation that we did 11 Q. You are assuming that your number is accurate. We didn't then try to validate 12 12 of reports for your TVT-O column came out of that FDA evaluated their own database the very same number of all mesh product 13 13 reports that FDA found? 14 accurately. 14 Q. Or even ran the same search that A. State that last sentence again. 15 15 you did to try to find the same number of 16 16 Q. Sure. For instance, in order to reports. Fair? reach your number here on your chart on the 17 17 18 A. Well, we downloaded TVT and TVT-O 18 first column that the percentage of TVT and TVT-O reports of pain for all SUI mesh 19 and any terms that were -- any like TVT 19 20 obturator, TVT-O, TVTO, we looked at 20 reports is 47.6 percent, you are assuming everything that was TVT, TVT-O. There are 21 that this number of TVT and TVT-O reports of 21 22 different ways that something may be 22 228 came out of this number, 479. represented. You know, the reports may 23 23 Aren't you making that assumption? 24 represent, for example, TVT-O in a different 24 A. Not exactly. way. TVT may be TVT or TVT classic or TVT 25 25 MR. GOSS: Objection. Form. Page 215 Page 217 retropubic. 1 THE WITNESS: I don't use the 1 2 There are various ways in which the 2 word "assume," and I'm not using it for 3 information may be, by product, recorded, 3 that basis. I'm saying that of 479 but it's all TVT or all TVT-O. We reports that FDA reported and with 4 4 5 downloaded all of those that were TVT and 5 Ethicon and TVT and TVT-O being one of 6 the major manufacturers, that if you 6 all that were TVT-O. 7 7 look at that number and you look at what O. I got that part. 8 A. I understand. 8 we were able to download for TVT-O, 9 Q. My question is: How are you 9 using that number, those numbers alone 10 validly comparing it to FDA's number of 479 10 standalone, but I wanted to compare what total complaints of pain without knowing percentage based on the total that FDA 11 11 what terms and how FDA did that search to had found, and if you look at the total 12 12 that FDA reported, I'm not assuming how 13 see if you'd come up with the same number of 13 total complaints of pain that FDA did? they did except that they said across 14 14 15 A. Well, FDA did this across nine 15 nine manufacturers, and one they based a manufacturers. I did not try and duplicate public health notification on this 16 16 FDA's data, but FDA said that this is what 17 17 information. 18 they found in their own MAUDE database, and 18 I didn't try and duplicate that I looked at the same information for the data, if that's what you're asking. But 19 19 20 same time period for TVT and TVT-O. So if 20 I didn't -- I looked at this based on 479 reports that they said they found 21 FDA's numbers were wrong, then --21 22 O. Or just different because they ran 22 across the manufacturers that they a different type of search than you did. looked at that I found this many 23 23 24 Isn't that possible? 24 reports. And that would be 47.6 percent 25 A. If you're downloading all nine 25 as the total.

Page 218 Page 220 1 BY MS. SUTHERLAND: 1 Q. Did you run -- well, tell me what 2 Q. Yeah. And my question just is: I 2 search you ran for TVT and TVT-O to allow 3 3 mean, aren't I correct that in order to get you to come up with 228 reports of pain. 4 your 47.6 percent of pain, that you're 4 A. It's in the exhibit -- it's in the 5 5 taking that 228 number of TVT/TVT-O reports Exhibit 1, I believe, to my report that and doing some sort of division with this 6 gives you -- that shows you the methodology, 6 7 479 number from FDA? 7 and it also provides a tabular presentation 8 8 for TVT and TVO by year of the numbers of A. Yes, that's correct. 9 Q. All right. And am I also correct 9 reports. 10 that you didn't do some sort of quality 10 Q. Yeah, and maybe I can cut to the 11 check to ensure that you would have found chase. Did you do a term search for "pain" 11 the same number of reports, meaning 479, to come up with the 228 MDRs? 12 12 with your search terms that you used to find 13 13 A. What you have to do in that -- when the TVT and TVT-O reports of pain? 14 14 you're doing a manual download, you have to MR. GOSS: Objection. Form. read through every event description, and we 15 15 THE WITNESS: Let me check one downloaded the information into an Excel 16 16 thing here quickly. It was in the database, and then you have to read through 17 17 18 2000 -- I just wanted to double-check my 18 every event description to pull out the figure of nine. It was in the 2008 FDA adverse events that are reported, and then 19 19 20 public health notification that they 20 we tabulated those in Access and did an assessment of total number of pain. 21 noted that the reports of complications 21 22 were from nine surgical mesh 22 Q. Okay. And so how are you able to 23 manufacturers of surgical mesh devices 23 tell me that the way that you did your 24 used to repair pelvic organ prolapse and 24 analysis to pull out the 228 reports of pain 25 stress urinary incontinence. That's for TVT and TVT-O would have gotten you the 25 Page 219 Page 221 where the nine. I just wanted to verify 1 same number that FDA got had you done it for 1 2 2 the nine manufacturers. all nine mesh manufacturers, the same number 3 Now to your specific question, 3 being 479? 4 I did not verify FDA's numbers, but I 4 A. Well, the information, whether I'm 5 think maybe there's a disconnect in 5 reviewing it or FDA is reviewing it, the 6 understanding that we pulled everything information that is in the event description 6 7 for TVT and TVT-O that we could find. 7 doesn't change, and that's where the 8 8 BY MS. SUTHERLAND: information is located. 9 Q. No, I got that. 9 Q. I guess what I'm getting at is do 10 A. And FDA pulled the information that 10 you know if a report listed pain, erosion, it found for manufacturers that made SUI and infection, did FDA put that report in 11 11 each separate row there for pain, erosion, 12 mesh products. 12 and infection? Or did it pick one and say, 13 Q. And I got that. 13 A. And I didn't verify that FDA did you know what? For this report, I'm going 14 14 15 their analysis correctly. I think that's 15 to put it just in erosion? what you're asking to do my percentage. MR. GOSS: Objection. Form. 16 16 O. No. I'm not asking whether or not THE WITNESS: Ethicon picked 17 17 18 FDA did it correctly. What I'm asking is 18 one. whether or not you ran a similar search for 19 19 BY MS. SUTHERLAND: pain as FDA did for pain when you were 20 Q. Well, I'm asking do you know how 20 finding your TVT and TVT-O reports. FDA did it so that you can say that your 21 21 percentage in this last column is valid 22 MR. GOSS: Objection, Form. 22 THE WITNESS: Yes, I did for based on you and FDA performing the same 23 23 search to reach the same numbers? 24 TVT and TVT-O. 24 BY MS. SUTHERLAND: 25 MR. GOSS: Objection. Form. 25

		1	
	Page 222		Page 224
1	THE WITNESS: Do you have the	1	For this number, the numbers of
2	executive summary? With my	2	patients with pain was exactly that.
3	recollection is this is the total number	3	The number of patients with pain, not
4	of patients in which they found pain,	4	the number of episodes of pain. As I
5	and they would have counted those	5	note here, the total number of reports
6	appropriately. They would have	6	is greater than the number of MDRs
7	accounted those separately. I don't	7	because most MDRs reported more than one
8	recall, as I sit here today, without	8	adverse event.
9	going back and looking at the	9	BY MS. SUTHERLAND:
10	information. I don't recall exactly	10	Q. Okay. I think I'm going to move to
11	how what they described as their	11	strike that answer.
12	methodology, but having done many	12	Would you read my question back.
13	adverse event assessments over the		, , ,
		13	(Record read by the
14	course of my career, if you if a	14	reporter as follows:
15	patient has pain and erosion and	15	THE WITNESS: I think I
16	infection, you don't just choose one of	16	answered that. I think I told you
17	them. You report every one.	17	MR. GOSS: Wait, wait. The
18	BY MS. SUTHERLAND:	18	ball is in her court.
19	Q. And do you know if that's what FDA	19	THE WITNESS: Sorry.
20	did in order to reach their numbers in that	20	BY MS. SUTHERLAND:
21	first column on page 123?	21	Q. Can you answer that question?
22	A. To the best of my recollection as I	22	MR. GOSS: That's what you get.
23	sit here today, that is correct, but I would	23	THE WITNESS: Sorry. I think
24	need to go back and review that. If you	24	I I answered that. I said that
25	have it, I'd be happy to take a look at it.	25	I've answered that in the last couple of
-			
	Page 223		Page 225
1	Page 223 I just I can't recall specifically that	1	Page 225 questions. If you have the document
1 2		1 2	
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2 3 4 5 6	I just I can't recall specifically that without looking back at the document.  Q. Did you make an attempt to perform your search and inclusion of reports in the same manner that FDA had as set out in what you're telling me is in the executive	2 3 4 5 6	questions. If you have the document that describes FDA, what FDA did, I can go back and just verify my recollection. Without that document, I'm giving you the best information I can with regard to my recollection
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	I just I can't recall specifically that without looking back at the document.  Q. Did you make an attempt to perform your search and inclusion of reports in the same manner that FDA had as set out in what you're telling me is in the executive summary?  MR. GOSS: Objection. Form.  THE WITNESS: I did the most comprehensive assessment we could do, which was to pull all the MDR reports for any description of TVT, any description of TVT-O, remove duplicates, and read through the event description, and every adverse event that was noted was recorded, and then our tabulations were done based on that.  With the point also that I was making that if the patient had several different types of pain reported, we didn't report that patient twice. We reported, and you'll see in the exhibit that you can see the total numbers of	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	questions. If you have the document that describes FDA, what FDA did, I can go back and just verify my recollection. Without that document, I'm giving you the best information I can with regard to my recollection BY MS. SUTHERLAND: Q. Okay. A as to how FDA what FDA did. What we did, you can't be more comprehensive than what we did Q. I know you're comprehensive. A for looking at TVT and TVT-O, and it was a very laborious process to go through each of these, and we were as conservative as possible, like removing duplicates, and clearly, and that's the appropriate way to report adverse events. You don't you know, if you're looking at total number of patients with pain, you don't count a patient twice if they had two different types of pain. So I followed the same methodology that I've

Page 226 Page 228 documents that you've seen, and you claimed 1 companies. 1 2 Q. Let me just close the loop on this 2 it's a lot, from that number of documents you've reviewed, has FDA ever said that the 3 just to be sure I have it in my head. Let 3 4 me pick another column here. Let's say 4 IFU for the TVT-O up to the time of implant 5 5 bleeding. In order to reach this was inadequate? 6 39.8 percent in the last column, what you're 6 A. You know, the way I'm going to 7 saying, as I understand it, that is the 7 answer that is I have not seen -- while I 8 total percent of reports attributed to TVT 8 have not seen any specific communications 9 and TVT-O out of all SUI reports from 2008 9 directed to Ethicon, the 2008 public health 10 to 2010? 10 notification includes information that --11 A. According to FDA's number of the 11 and recommendations that indicate what a number of patients that -- the number of MDR 12 12 manufacturer should do and recommendations reports, I should say, which should be 13 13 for what physicians need to know. individual patients, had bleeding. There 14 14 O. Where are the recommendations that the FDA said a manufacturer ought to do with 15 were 103. 15 respect to its IFU in the 2008 PHN? 16 Q. Right. And let me stop you there 16 because, as I understand it, you did not do A. The IFU is a communication, as 17 17 18 the same search that FDA did to come up and 18 we've discussed before, the primary verify that you also would find 103 reports? 19 communication between the manufacturer. 19 20 MR. GOSS: Objection. Form. 20 Q. Now, I want you to answer my 21 THE WITNESS: Yes. I did not 21 auestion. look at all the other manufacturers. 22 22 A. I am. But it has a basis, and the 23 23 basis is that it is the manufacturer's That's correct. 24 BY MS. SUTHERLAND: 24 communication with the physician, and these 25 Q. Okay. So you're assuming in order 25 recommendations say that the physician Page 227 Page 229 to reach this 39.8 percent that your number 1 should be vigilant for potential adverse 1 2 2 of 41 reports comes out of this number, 103 events, especially erosion and infection, 3 3 watch for complications associated with the reports? 4 tools, inform patients that implantation of MR. GOSS: Objection. Form. 4 5 THE WITNESS: Based on the 5 surgical mesh is permanent, that some 6 number of bleeding reports that FDA 6 complications associated with the implanted 7 7 mesh may require additional surgery that may reported, we took a percentage of that 8 8 or may not correct the complication, inform to arrive at what percentage of that patients about the potential for serious 9 number was TVT and TVT-O. 9 BY MS. SUTHERLAND: 10 complications and their affect on quality of 10 Q. Okay. I'm going to change gears. life, including pain during sexual 11 11 12 A. Okav. 12 intercourse, scarring and narrowing of the vaginal wall, noted there in POP repair, and 13 O. And get back on my outline. 13 Has the FDA ever said that the provide patients with a copy of the patient 14 14 15 TVT-O IFU up to the time of implant in this 15 labeling from the surgical mesh case was inadequate? manufacturer. 16 16 MR. GOSS: Objection. Form. There is testimony by Ethicon, and 17 17 18 THE WITNESS: I'm not -- there 18 if I recall correctly as I sit here today, specifically from Dr. Hinoul testifying that 19 may be internal communication to which 19 20 I've not seen, but based on what I've 20 all of the information in the 2008 public 21 seen, the answer to that is, no. 21 health notification was included in the TVT 22 BY MS. SUTHERLAND: 22 and TVT-O IFU, and it was not. Q. All right. Let me ask it cleanly. 23 23 But that information -- and I think As far as documents that you have seen --24 24 it maybe even -- that publicly, if I'm 25 and we've talked about the number of 25 recalling correctly as I sit here today -- I

			1
	Page 230		Page 232
1	can actually verify that.	1	included.
2	Q. I've got to say you're not	2	Q. Move to strike everything after
3	answering my question.	3	"no."
4	A. Oh, I am answering your question	4	Is the TVT-O mentioned anywhere in
5	because the fact that physicians should do	5	the 2008 PHN by name?
6	these things, it's up to the manufacturer to	6	A. Not by name.
7	communicate this information to the	7	Q. All right. Has FDA ever issued a
8	physicians through the IFU.	8	warning letter to Ethicon about the TVT-O?
9	So while this is a public health	9	A. No, not that I not that I've
10	notification, and the FDA is telling the	10	seen, and I have looked, yes.
11	physicians what the manufacturer should have	11	Q. I bet you looked.
12	told the physicians.	12	We're at 30 minutes. Do you want
13	Q. Is there a document where the FDA	13	to go off and check?
14	ever told Ethicon your TVT-O IFU is	14	A. Yes, please. Thank you.
15	inadequate up to the date of implant?	15	THE VIDEOGRAPHER: With the
16	MR. GOSS: Objection. Form.	16	approval of counsel, going off the
17	THE WITNESS: I believe I've	17	record. The time is approximately 3:00
18	answered that.	18	p.m.
19	BY MS. SUTHERLAND:	19	(Recess taken from
20	Q. You're pointing to the PHN?	20	3:00 p.m. to 3:09 p.m.)
21	A. I'm pointing to the PHN.	21	THE VIDEOGRAPHER: With the
22	Q. Is there anything besides the PHN	22	approval of counsel, back on the record.
23	that you can point me to where you're saying	23	The time is approximately 3:09 p.m.
24	FDA told Ethicon the TVT-O IFU is	24	BY MS. SUTHERLAND:
25	inadequate?	25	Q. Dr. Pence, have you ever seen a
	Page 231		Page 233
1	Page 231 A. If you read the 2008 public health	1	Page 233 document where FDA determined that the TVT-O
1 2	A. If you read the 2008 public health communication and you compare	1 2	document where FDA determined that the TVT-O device was misbranded?
	A. If you read the 2008 public health communication and you compare Q. I said other than		document where FDA determined that the TVT-O device was misbranded?  MR. GOSS: Objection. Form.
2 3 4	A. If you read the 2008 public health communication and you compare Q. I said other than A. I know, but if you compare that	2 3 4	document where FDA determined that the TVT-O device was misbranded?  MR. GOSS: Objection. Form.  THE WITNESS: No.
2 3 4 5	A. If you read the 2008 public health communication and you compare Q. I said other than A. I know, but if you compare that I can't tell you about a specific document	2 3 4 5	document where FDA determined that the TVT-O device was misbranded?  MR. GOSS: Objection. Form.  THE WITNESS: No.  BY MS. SUTHERLAND:
2 3 4	A. If you read the 2008 public health communication and you compare Q. I said other than A. I know, but if you compare that I can't tell you about a specific document from FDA to Ethicon, but if you compare	2 3 4	document where FDA determined that the TVT-O device was misbranded?  MR. GOSS: Objection. Form.  THE WITNESS: No.  BY MS. SUTHERLAND:  Q. All right. In fact, as far as you
2 3 4 5 6 7	A. If you read the 2008 public health communication and you compare Q. I said other than A. I know, but if you compare that I can't tell you about a specific document from FDA to Ethicon, but if you compare what's supposed to be notified to physicians	2 3 4 5 6 7	document where FDA determined that the TVT-O device was misbranded?  MR. GOSS: Objection. Form.  THE WITNESS: No.  BY MS. SUTHERLAND:  Q. All right. In fact, as far as you know, FDA has never determined TVT-O to be
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Page 234 Page 236 510(k); right? 1 O. Has FDA ever recalled the TVT-O? 1 2 A. Not to my knowledge, as I sit here 2 A. It was. My recollection also is, 3 3 though, that Ethicon had brochures for the today. 4 4 TVT family of product at the time of that Q. All right. Have you ever spoken --5 have you ever spoken with a woman who had 5 submission, and, to the best of my the TVT-O implanted in her? 6 recollection as I sit here today, and I can 6 7 MR. GOSS: Objection. Form. 7 look it up, did not include the patient 8 8 labeling in the 510(k), and what is intended Foundation. 9 THE WITNESS: Yes. 9 to be included in a 510(k) would also BY MS. SUTHERLAND: 10 10 include patient labeling if a company is 11 Q. Would that be a plaintiff? 11 going to be using it. Let me just take a A. Yes. 12 12 moment here to check something. 13 Q. All right. Which plaintiff? 13 Yes, as stated on page 92 of my A. That would have been Ms. Batiste. 14 14 report, the patient brochure was not Q. Okay. You haven't talked to included for FDA's review in the proposed 15 15 labeling section of the 510(k) pre-market Ms. Ramirez? 16 16 A. No, I have not. notification for the TVT-O, although a 17 17 18 Q. All right. Have you ever done any 18 patient brochure had been available since kind of survey to determine what women 19 2001 for the TVT system, and noting also 19 20 perceived from the patient brochure for the 20 that the information that is intended to be 21 TVT-O? 21 used required in a pre-market notification, 22 A. No. I have not done such a survey. 22 submission includes proposed labeling and advertisement sufficient to describe the 23 And just to clarify, Ms. Batiste, I spoke to 23 her in the context of being courteous when I 24 device's intended use and its directions for 24 was at trial, but I didn't discuss any 25 25 its use -- and the directions for its use. Page 235 Page 237 specifics obviously with her. 1 Q. Now, at the time of the submission 1 2 2 of the TVT-O 510(k), was there in existence Q. Yeah. 3 For the Class 2 device TVT-O, is 3 a TVT-O brochure? 4 4 there a requirement that Ethicon have a A. The --5 patient brochure? 5 MR. GOSS: Objection. Form. 6 A. There isn't a requirement unless 6 THE WITNESS: There was -- if 7 7 the FDA requests it. you look at my report on page 92, in the 8 8 Q. Okay. Did the FDA request one for documents that were available for my 9 the TVT-O? 9 review, there were 16 patient brochures A. Do you have the 510(k)? I'd have 10 final copy relevant to the TVT-O product 10 to go back -with the following dates, and one of 11 11 O. I don't have the 510(k). those was dated 2004. 12 12 13 A. -- and look. They did -- they 13 The submission went in in 2003, the 510(k) submission went in in 2003, 14 had --14 15 15 but as I noted, many of these are the MR. GOSS: I can probably let TVT family of products and contain very 16 you see one. 16 similar information, and my opinion MS. SUTHERLAND: I don't want 17 17 18 to take the time. 18 would be that they certainly could have included one in the 510(k) submission. 19 Do you recall, as you sit here 19 20 today, whether or not FDA requested a 20 They had TVT ones since 2001 at least. 21 patient brochure for TVT-O? 21 BY MS. SUTHERLAND: 22 THE WITNESS: My recollection 22 O. Let me get an answer to my question, though, because I think my 23 is they did not. 23 24 BY MS. SUTHERLAND: 24 question was, was there in existence at the 25 25 time of the submission of the TVT-O 510(k) a Q. Yeah, because it was a special

Page 238 Page 240 TVT-O brochure? That answer is no, isn't 1 1 includes proposed labels, labeling and 2 2 advertisement sufficient to describe the 3 3 A. The ones that were made available device, its intended use and directions 4 4 to me began in 2004, which was the same time for its use. 5 5 period they marketed the product. So if -- since Ethicon 6 Q. All right. I'm still not hearing 6 obviously intended to include patient 7 an answer to my question. Was there in 7 labeling and make that available, it 8 existence at the time of the submission of 8 would have been appropriate for them to 9 the TVT-O 510(k) a TVT-O brochure? 9 include patient labeling in their 510(k) 10 A. Not one specific to the TVT-O, but 10 submission. 11 there were TVT ones, and as I noted, many of 11 BY MS. SUTHERLAND: these brochures are not specific to TVT or 12 Q. Now, did you see documents that 12 reference an intent by Ethicon to have a 13 TVT-O. They are for the TVT family of 13 patient brochure for TVT-O before clearance 14 products. 14 Q. I'm going to move to strike 15 15 of TVT-O? everything after "Not one specific to the MR. GOSS: Objection. Form. 16 16 TVT-O." THE WITNESS: I don't -- I 17 17 18 For those brochures that you're 18 don't recall specifically, as I sit here talking about that were for the TVT family today, except to say that they had had 19 19 20 of products, they didn't include TVT-O until 20 TVT patient labeling in existence since after TVT-O was cleared by FDA, now, did 21 2001. 21 22 thev? 22 BY MS. SUTHERLAND: 23 MR. GOSS: Objection. Form. 23 Q. Okay. Do you intend to offer an 24 THE WITNESS: No, but they 24 opinion as to a safer alternative design for 25 could just as the IFU for TVT-O was 25 the TVT-O? Page 239 Page 241 included in the 510(k), because there 1 A. If asked, I would offer that 1 2 2 were brochures that were existing for opinion. 3 TVT since very shortly thereafter and 3 Q. I mean, do you have that in your for launch, there was a -- there was one 4 4 report? 5 that included TVT-O to comply with 5 A. I talk about mesh fraying, and I 6 the -- what should be included in the 6 talk about the laser-cut mesh versus the 7 510(k), Ethicon could readily have used 7 mechanically cut mesh and various issues 8 8 with the mechanically cut mesh. what it had and made any additions for 9 TVT-O and submitted it in the 510(k) but 9 Q. Would it be your opinion that 10 did not. 10 laser-cut mesh is safer than mechanically BY MS. SUTHERLAND: 11 11 cut mesh? 12 O. I want to move to strike everything A. The testing wasn't done on the 12 laser -- they both have issues. They both 13 after "no." 13 have different issues, and the testing was 14 Based on what was in existence with 14 15 respect to a TVT-O brochure, are you opining 15 never done to -- clinically to determine that Ethicon breached some standard or head to head how they compare. 16 16 regulation by not creating a TVT-O brochure O. So do you intend to after an 17 17 18 to include with its 510(k) submission? 18 opinion that laser-cut mesh is safer than MR. GOSS: Objection. Form. mechanically cut mesh in this trial? 19 19 20 THE WITNESS: Well, as I note 20 MR. GOSS: Objection. Form. in the information and referencing the THE WITNESS: No. I'm saying 21 21 22 quidance on medical device patient 22 that there were issues with mechanically 23 labeling, which was a 2001 guidance, the cut mesh. There were also issues with 23 information that's required in a the laser-cut mesh, and the testing was 24 24 25 pre-market notification submission 25 never done to assess whether or not,

		1		
	Page 242			Page 244
1	with either one, the implications of the	1	literature using those meshes in the	-
2	issues with both what the	2	surgical treatment of stress urinary	
3	implications were for the patient.	3	incontinence?	
4	BY MS. SUTHERLAND:	4	A. Those particular meshes?	
5	Q. Move to strike everything after	5	Q. Correct.	
6	"no."	6	A. Not that I've seen at this point	
7	Are you aware let me ask it this	7	· · · · · · · · · · · · · · · · · · ·	
8	way: In 2010 at the time of implant, was		today for Ethicon.	
9	there available a mesh sling that, in your	8	Q. Because there's not any.	
10	opinion, was safer than the TVT-O?	9	A. I know.	
11	MR. GOSS: Objection. Form.	10	Q. Right?	
12	Foundation.	11	A. That's correct.	
13	THE WITNESS: Based on there	12	Q. All right.	
14	were meshes available	13	A. Because they didn't develop it for	
15	BY MS. SUTHERLAND:	14	SUI. They didn't take it to that step where	
16	Q. Answer my question now.	15	they had meshes that could have they	
17	A that were considered safer than	16	believed could have been safer but never	
18	the heavy weight mesh that is in the TVT-O,	17	developed the sling with such meshes.	
19	and Ethicon had such meshes.	18	Q. I'm going to move to strike.	
20	Q. I'm going to move to strike.	19	Let's change gears and talk about	
21	Would you read back my question,	20	adverse events. If you'll flip to page 125	
22	please?	21	of your report, are you with me?	
23	(Record read by the	22	A. Yes.	
24	reporter as follows:	23	Q. Okay. Now, in reading your report,	
27	Let me ask it this way: In 2010 at the time of	24	as I understand it, you have I'm going to	
25	implant, was there available a mesh sling that, in	25	talk about these in different buckets.	
23	implant, was there available a mesh sing that, in	23	taik about these in different buckets.	
	Page 243			Page 245
1	Page 243	1	A Okay	Page 245
1 2	your opinion, was safer than the TVT-O?")	1 2	A. Okay.	Page 245
2	your opinion, was safer than the TVT-O?")  THE WITNESS: I've not done an	2	Q. So in my first bucket, I'm going to	Page 245
2	your opinion, was safer than the TVT-O?")  THE WITNESS: I've not done an evaluation of all mesh slings that were	2	Q. So in my first bucket, I'm going to talk about the reports that you're claiming	Page 245
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	your opinion, was safer than the TVT-O?")  THE WITNESS: I've not done an evaluation of all mesh slings that were available; so I can't I can't answer that question.  BY MS. SUTHERLAND: Q. Okay. So you aren't intending to offer an opinion that there was some mesh sling that was available in 2010 that was safer than TVT-O; correct?  MR. GOSS: Objection. Form. THE WITNESS: As you've asked the question, that is correct. If asked, I will opine that there were meshes available by Ethicon's own documentation and testimony that would that they believed would be safer than the heavy weight mesh used in TVT-O.  BY MS. SUTHERLAND: Q. And are you talking about Ultrapro?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. So in my first bucket, I'm going to talk about the reports that you're claiming were reportable but were not given to FDA. Okay?  A. Yes. These are examples. Q. Examples. Now, you list 29 examples; correct? A. Yes. Q. And that is somewhere in your report, and then the full section of the 29 is in Exhibit 4 to your report; correct? A. Yes. Q. All right. The first thing I want to ask you is: Are you intending to specify any other issue reports other than the 29 that you specifically delineated that should have been reported to FDA but were not? A. As I sit here today MR. GOSS: I'm sorry I didn't hear the last part of that. Would you ask that again? MS. SUTHERLAND: I don't know	Page 245
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Page 246 Page 248 back? don't have a specific number that I'm going 1 1 2 (Record read by the 2 to say should have been reported but were 3 reporter as follows: 3 not reported but that there were a number The first thing I want to ask you is are you 4 that were not reported that should have been 4 intending to specify any other issue reports other 5 reported. 5 than the 29 that you specifically delineated that 6 And because of the importance of 6 should have been reported to FDA but were not?") 7 reporting so that, for example, the 2008 7 THE WITNESS: As I sit here 8 public health notification, if companies are 8 today, no. 9 not fulfilling their responsibilities for 9 BY MS. SUTHERLAND: 10 reporting MDRs according to the requirements 10 Q. Okay. 11 for reporting, then that information doesn't 11 A. If there are some that are 12 populate the database, and FDA doesn't 12 presented to me, and I'm asked about them, I 13 become aware, nor do other people who may would opine about them. 13 14 be, like physicians, who -- we talked about O. Tell me how you found those 29. 14 15 different sources of information -- who may 15 What was your methodology to pull out those 16 access the MDR database or patients to 16 29? 17 see -- because it is a publicly available 17 A. If you look at page -- at the 18 database to see what information exists. bottom of page 124, I note that an issue 18 19 That information is not there. report -- what an issue report is and that 20 So it's not a true picture, and we 20 there were 862 TVT issue reports from 1999 21 talk about there's a lot of underreporting, to 2012 and 901 TVT-O issue reports from 21 22 and this is one of the reasons there's 22 2004 to 2012 that I received and reviewed 23 underreporting. There are other reasons for 23 for the preparation of my TVT and TVT-O 24 underreporting to the MAUDE database as 24 reports. 25 25 well, but FDA, if they get the information And I was able by matching up Page 247 Page 249

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the -- what was in the MAUDE database to the issue reports, I was able to determine that Ethicon submitted 70 percent as MDR reports to FDA for TVT, and I determined then that 29.9 percent or 258 were determined to be not reportable by Ethicon. And then one was undetermined.

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For TVT-O, 444 or 49.3 percent were submitted as MDR reports to FDA and 457 or just over 50 percent, 50.7 percent, were determined by Ethicon to be not reportable.

So I reviewed the issue reports that Ethicon determined to be not reportable, and they showed that -- my review showed that a number of them met the requirements for MDR reporting and should have been submitted to FDA, in my opinion. And I took examples of those that Ethicon determined were not reportable and included those in my report.

Q. All right. Now, are you intending to offer an opinion that some number more than 29 should have been reported to FDA?

A. I don't have a specific number, if I understand your question correctly. I 1 sooner, then that 2008 public health 2

notification may have come out sooner than it did if all manufacturers were fulfilling their responsibilities for reporting.

Q. All right. I'm going to move to strike everything after your first sentence where, I think, you said you were going to say a number had not been reported to FDA.

My question is: Are you going to offer an opinion that more than 29 issue reports should have been reported to FDA?

A. I might offer that opinion.

O. And what is that opinion based on? I mean, do you have those?

A. Yes.

Q. Do you have those issue reports other than the 29 that you can tell me that you say ought to be -- ought to have been reported?

A. I can't tell you, as I sit here today. I have them available if I -- there are others if I wanted -- these are not the only 29. There are others.

24 Q. Okay. Where are those others? You 25 say you have them available. I want to see

63 (Pages 246 to 249)

Page 250 Page 252 A. Yes. And if I'm asked -- if that's 1 them. 1 2 2 going to be asked --A. In my records. 3 3 Q. Did you create an Excel workbook on MR. GOSS: I'm sure she'll ask 4 your MAUDE database review? 4 me. 5 5 A. Well, this is separate. These are THE WITNESS: I can certainly 6 6 issue reports. do that. 7 Q. Then I'll ask that separately. 7 BY MS. SUTHERLAND: 8 8 Where -- so if I want to -- I mean, O. I've got a letter drafted in my 9 I'm entitled to know, you know, what your 9 head already. 10 opinions are, and I've got your 29 issue 10 Okay. Now, those 29 examples that 11 reports that you say were not appropriately 11 you pulled out are all on TVT; correct? 12 reported to FDA. 12 A. Yes. 13 If you're going to say some number 13 Q. All right. Did you perform a review of the issue reports for TVT-O that 14 more than that 29 should have been reported 14 to FDA, I need you to tell me, number one, 15 15 were not submitted to FDA? what that number is, and number two, which A. Yes, I did. I don't recall, as I 16 16 specific issue reports those are. sit here today, if I went through all of the 17 17 18 A. I understand what you're asking. I 18 457 that Ethicon determined to be not think where our disconnect may be, you asked 19 19 reportable, but I certainly went through a 20 if I was going to say more than 29 should 20 number of them. have been reported. I don't intend, as I 21 Q. Okay. Are you going to offer any 21 sit here today, unless asked by counsel, to opinion that any of the TVT-O issue reports 22 22 tally the total number. were not appropriately submitted to FDA? 23 23 24 I don't anticipate being asked how 24 A. If asked, if asked that, yes. I many should be reported -- should have been might not give a specific number, but I 25 25 Page 251 Page 253 reported that were not of the issue reports, 1 would say, yes, if asked that, I would 1 2 2 but if there were more than 29, these are respond that there were reports that were 3 3 not appropriately reported. examples. 4 So as I understood your question, 4 And the idea here is not so much a 5 you said are you going to say there were 5 specific number, but the real underlying more than 29, and I could say there were point is that Ethicon was down playing the 6 6 7 more than 29 without giving an actual 7 adverse events that occurred using 8 number. There were also the malfunctions. 8 rationales for not reporting that were 9 Q. Well, and I'll get to malfunctions. 9 inappropriate, and as a result, not 10 But if you have an opinion that more than 29 10 fulfilling its obligations that is required, issue reports ought to have been reported to both by FDA regulations and the global 11 11 FDA, and as I understand your testimony, you 12 standard of care. 12 know which issue reports those are --13 13 And as a result of that, then that A. I would have to go -compromises the ability of the FDA and 14 14 15 Q. -- I would ask counsel that he let 15 others to see what the true safety profile, me know which ones they are so that we and it -- true safety profile of these 16 16 products are -- or is. And the other aspect aren't ambushed at trial. I'm entitled to 17 17 18 know --18 of that is this all goes to the central principles of safety and performance. 19 A. I understand. 19 20 Q. -- which issue reports you think 20 Q. You've gone way past my question 21 should have been reported. 21 now. 22 MR. GOSS: Is there a question 22 A. But it's all relevant. It's all 23 in there somewhere? 23 relevant. 24 BY MS. SUTHERLAND: 24 MS. SUTHERLAND: Would you read 25 25 my question back, please? Q. Does that sound fair?

Page 254 Page 256 had not been appropriately reported to FDA 1 (Record read by the 1 2 reporter as follows: 2 for TVT-O? 3 A. Yes. 3 Are you going to offer any opinion that any of the 4 TVT-O issue reports were not appropriately 4 Q. Did they report to FDA some reports 5 5 submitted to FDA?") of leg pain? 6 BY MS. SUTHERLAND: 6 A. To the best of my recollection -- I 7 Q. All right. And I think you told me 7 would have to look back. Yes. 8 8 Neuromuscular problems. I'd have to look yes, you are. 9 A. If asked. 9 back at exactly what the reports were. Q. Okay. Now, how many --10 Q. Now, which issue reports for TVT-O 10 11 were not appropriately reported to FDA? 11 A. Oh, I can do that actually. A. I don't have them with me today. Q. You answered my question. 12 12 O. Do you have that somewhere? A. There's difficulty walking. It's 13 13 in my Exhibit 1. 14 A. Yes. 14 Q. How many reports of leg pain for 15 Q. All right. And I'm going to ask 15 counsel to get me those. TVT-O were not appropriately reported to 16 16 Do you know what number you're FDA, in your opinion, from what you 17 17 18 going to say -- or strike that. 18 reviewed? Do you know what number you found 19 A. I can't give you a number, as I sit 19 20 of the TVT issue reports were not 20 here today, and I also only received a appropriately reported to FDA? 21 certain number of issue reports. It's my 21 22 A. I don't recall the number, as I sit 22 understanding, drawing from the recesses of my memory from having done this a year or 23 here today. 23 24 Q. All right. Do you know what the two ago, I didn't receive all issue reports. 24 25 reports were in those issue reports that 25 The issue reports I received I went through, Page 255 Page 257 you're saying were not appropriately 1 and I've given you the numbers of those 1 2 reported to FDA, meaning erosion, extrusion, 2 which were reported as MDRs, which were not, 3 3 and I can't tell you exactly, as I sit here pain? today, how many should have been reported 4 A. There were a variety of different 4 5 adverse events. 5 but that were not of the issue reports that 6 Q. All right. What were they? I was given to review and had access to. 6 A. Difficulty walking, pain, urinary 7 7 O. And as I understand it, you also 8 listed ten malfunctions as examples of issue 8 issues, for example. 9 Q. Okay. Now, did you look at what 9 reports that were not reported to FDA and 10 was reported to FDA with respect to TVT-O's 10 should have been? issue reports? 11 A. Yes. 11 12 A. Yes. 12 Q. All right. Now, that's all for 13 Q. All right. Did they report reports 13 TVT; correct? of pain to FDA? 14 14 A. Yes. 15 A. Yes, and we know that because we 15 Q. Do you have a number that you just went through the tabular presentation. determined over ten that should have been 16 16 Q. You answered. You said yes. 17 17 reported to FDA? 18 Did they report reports of urinary 18 A. I don't recall the specific number. dysfunction to FDA? Again, these are examples. 19 19 20 A. Yes, but that's not the issue 20 Q. Yeah. My question is: Do you have whether they reported some. It's whether or more than ten that you found that you 21 21 thought should have been reported to FDA? 22 not they reported all that should have been 22 reported. A. I would have to go back and tally 23 23 24 Q. Did they report -- I think you said 24 the number. that there was some reports of leg pain that 25 Q. Okay. Did you look for 25

Page 258 Page 260 malfunctions in TVT-O issue reports and 1 all, did FDA take any compliance action 2 determine that any should have been reported against Ethicon for these 36 reports that were late anywhere from 1 to 19 days? 3 to FDA but were not? 3 4 4 A. To the best of my recollection as I A. No. But I have seen, to answer 5 5 where I think you're going with your sit here today, yes. Q. And how many? 6 question, FDA does --6 7 A. I can't give you a number without 7 Q. I think you answered my question. 8 going back and checking. 8 A. -- does note in warning letters if 9 Q. And do you know what type of 9 something has not been reported or in a 483 10 malfunction? 10 report, but also to your question you asked me about compliance, and FDA did issue a 483 11 A. I don't recall specifically, as I 11 12 sit here today. 12 related to compliance. Q. That was a 483 observation in 2005; 13 Q. Okay. But you have all of that 13 information somewhere back at your office, 14 14 right? A. Uh-huh. 15 if I'm correct? 15 A. Yes. 16 16 Q. And then that was responded to by 17 Q. Okay. Now, you also listed some 17 Ethicon; correct? 18 late reports that -- meaning Ethicon got 18 A. To the best of my recollection, them and waited longer than 30 days to yes. If not, that would be an issue. 19 19 20 report them to FDA? 20 Q. And no further action was taken by A. Yes. 21 FDA, was it? 21 22 Q. Now, as I understand it -- well, 22 A. To the best of my knowledge, that's 23 let's look on page 124. What you found 23 correct. specific to TVT-O were 36 late reports; is 24 Q. All right. And no -- certainly no 24 25 that right? 25 compliance action was taken as a result of Page 259 Page 261 A. Yes. 1 that 483 observation; right? 1 2 O. All right. And as I understand it, 2 A. Yes, but understanding that when they were late from 1 day to 19 days; is 3 FDA performs an inspection, it's based on 3 something very limited, and FDA has not had 4 that right? 5 A. Yes. 5 access to all of the information that I have 6 6 Q. All right. Now, are you saying had access to. 7 7 Q. Move to strike everything after that that delay of 36 reports from 1 day to 19 days is of some sort of significance? 8 "yes." 8 9 A. Yes. It's out of regulatory 9 All right. The issue reports that 10 compliance. 10 were reviewed for TVT and TVT-O, did you Q. Is it -actually review them? 11 11 12 A. It's a violation of the A. Yes. 12 regulations. 13 13 O. Did you have help reviewing them? A. Yes, I did. 14 Q. Is it of significance in the 14 15 evaluation of the risk of TVT-O? 15 Q. And who was that? A. For that time frame, I would think A. It would have been several 16 16 that particular time frame didn't make a different people over time. 17 17 18 difference in terms of FDA's evaluation. 18 Q. Who all? A. Dr. Miriam Erberich would have been 19 O. I wouldn't think so either. 19 20 A. However, the requirements are set 20 one of them, potentially Dr. Kathryn Kimmel, for a reason, and they are supposed to be 21 21 Wren Cherney, Andrea Friedman. To the best of my recollection as I 22 followed, and it is a violation of their 22 requirements, FDA requirements, not to sit here today, those would be the staff who 23 23 would have assisted me with looking at 24 submit within 30 days. 24 25 Q. Have you seen FDA -- well, first of 25 those. But any that I determined, any that

Page 262 Page 264 were determined and that I've discussed as Q. Okay. Did you look at how many of 1 1 2 being they should have been reported but 2 the reports were based on filed lawsuits? 3 3 were not, that was all my evaluation. A. I did take a look at that more 4 Q. Okay. So we know for the 29 that 4 recently, not so much in the number that I 5 5 are listed, you reviewed those. recall to speak about but the percentage. 6 At various times -- and I would have to go A. Yes. 6 7 Q. And we know for the 10 malfunctions 7 back and look at the information to verify 8 8 that were listed, you reviewed those. my memory whether it was 2012 -- I think it 9 A. Absolutely. 9 was 2012 to 2014 that we looked at. It 10 Q. And if I'm understanding your 10 could have been 2013 to 2015. I would have 11 testimony, you reviewed others that you're 11 to go back and just double-check the years, not able to tell me about today that you 12 12 but based on an assessment of the event claim should have been reported to FDA. description, if attorney reported was 13 13 14 A. Yes. I just can't recall the 14 mentioned, in one of the years, it was 15 specifics of those, and where people would 15 35 percent. One year -- on one of the years, it have helped me would have been to, for 16 16 example, to determine which ones were was -- I looked at TVT and TVT-O, and they 17 17 18 actually reported to FDA of the issue 18 were both very similar. It was around reports because we had to match that 35 percent, and then one year it was 80 to 19 19 20 information up with the MAUDE database and 20 81 percent, and then in the subsequent year, verify that the ones that were not 21 it was about 50 percent. 21 Q. Okay. What year was it 80 to 22 reportable we could not find MDR reports 22 23 that were associated with those. So that's 23 81 percent? 24 where they would have helped me. 24 A. That's what I'm trying to remember if we looked at 2012 to 2014 or 2013 to 25 Then the other aspect that I asked 25 Page 263 Page 265 them to help me with was to go through the 1 2015, and I have to go back and look at my 1 2 2 different issue reports and read through records. I just can't -- I don't want to them and categorize them according to what 3 confirm without double checking my memory. 3 the adverse reaction was. Was it difficulty 4 4 Q. Okay. There was a reference -- if 5 walking? Was it a urinary problem? Was it 5 you turn to your Exhibit 1 of your report, erosion? What was it so that I'd have those which was the MAUDE database in your 6 6 in the categories, and then I could go 7 7 report --8 8 through and individually review them as to A. Okay. what was reportable or whether it was a 9 Q. -- and on the second page, middle 10 malfunction function and whether it was 10 of the page --A. The table. 11 reportable or not. 11 O. How were duplicates culled out? O. I'm sorry. First page. 12 12 13 A. The -- in two ways: We look at the 13 A. Oh, I'm sorry. -- to see if -- sometimes you'll have the Q. There's a reference there, fourth 14 14 15 same report number. It will appear more 15 paragraph down, "All such MDRs were reviewed than once in your download, and we get rid and an Excel workbook was created to record 16 16 of anything of that nature. 17 17 the information provided by the adverse 18 Also -- and I think I have a 18 events." description in here as well, but also we 19 19 Do you see that? would read through -- as I mentioned, we 20 20 A. Yes. 21 read through the event descriptions, and if 21 Q. Do you have that Excel workbook? 22 it looks like everything is the same, and we 22 A. It should be in our archives. can verify that everything appears to be the 23 23 Q. Okay. A. We did change servers. 24 same in the reports, then we would not 24 report it twice. 25 Q. Here we go, Hilary. 25

	Page 266		Page 268
1	A. It's the truth. We did. It should	1	times Ethicon tried to follow up but yet got
2	be there.	2	no more information?
3	Q. All right. I'm going to send a	3	A. That alone does not. My own review
4	request for that. You won't have any	4	of the information, I found a number of
5	heartburn turning that over to me, would	5	instances where the investigation was very
6	you?	6	limited.
7	MR. GOSS: Send it to me. Send	7	Q. Can you give me an example of a
8	the request to me.	8	particular issue report?
9	MS. SUTHERLAND: I'll send it	9	A. I can't without going back and
10	to you.	10	looking at my records.
11	///	11	Q. Okay.
12	BY MS. SUTHERLAND:	12	A. But hold on just a minute. Let me
13	Q. Did you rely on that for some of	13	see if I can locate anything that would help
14	the opinions in your report?	14	to address your question.
15	A. Yes. We downloaded the information	15	Q. I've forgotten what my question
16	into the Excel workbook.	16	was.
17	Q. Yeah. And then you used that Excel	17	Would you read it back?
18	workbook when you were formulating some of	18	(Record read by the
19	your opinions; right?	19	reporter as follows:
20	A. Yes. We		Can you give me an example of a particular issue
		20	report?")
21	MR. GOSS: Objection. Form.	21	BY MS. SUTHERLAND:
22	BY MS. SUTHERLAND:	22	Q. I know you said no to that.
23	Q. And some of the charts that you've	23	Are you looking for an average of
24	had in your report?	24	attempts at follow up that might be in your
25	A. Yes. Exactly.	25	report somewhere?
	Page 267		Page 260
	Page 267	1	Page 269
1	Q. All right. Do the MDR reports set	1	A. No. That wouldn't be there, but I
2	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it	2	A. No. That wouldn't be there, but I was going to I was looking to see if I
2 3	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of	2 3	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific
2 3 4	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.	2 3 4	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question;
2 3 4 5	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.  A. Right.	2 3 4 5	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question; right?
2 3 4 5 6	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.  A. Right.  Q. Do you know how many of those women	2 3 4 5 6	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question; right?  Q. Well, it was, and I thought you
2 3 4 5 6 7	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.  A. Right.  Q. Do you know how many of those women reporting dyspareunia actually had it before	2 3 4 5 6 7	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question; right?  Q. Well, it was, and I thought you said you couldn't come up with one, as you
2 3 4 5 6 7 8	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.  A. Right.  Q. Do you know how many of those women reporting dyspareunia actually had it before any kind of mesh device was implanted?	2 3 4 5 6 7 8	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question; right?  Q. Well, it was, and I thought you said you couldn't come up with one, as you sit here.
2 3 4 5 6 7 8 9	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.  A. Right.  Q. Do you know how many of those women reporting dyspareunia actually had it before any kind of mesh device was implanted?  MR. GOSS: Objection. Form.	2 3 4 5 6 7 8 9	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question; right?  Q. Well, it was, and I thought you said you couldn't come up with one, as you sit here.  A. Right. Then I decided to look at
2 3 4 5 6 7 8 9	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.  A. Right.  Q. Do you know how many of those women reporting dyspareunia actually had it before any kind of mesh device was implanted?  MR. GOSS: Objection. Form.  THE WITNESS: No, not	2 3 4 5 6 7 8 9 10	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question; right?  Q. Well, it was, and I thought you said you couldn't come up with one, as you sit here.  A. Right. Then I decided to look at my report.
2 3 4 5 6 7 8 9 10	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.  A. Right.  Q. Do you know how many of those women reporting dyspareunia actually had it before any kind of mesh device was implanted?  MR. GOSS: Objection. Form.  THE WITNESS: No, not without not without going back and	2 3 4 5 6 7 8 9 10	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question; right?  Q. Well, it was, and I thought you said you couldn't come up with one, as you sit here.  A. Right. Then I decided to look at my report.  For example, on page 26, this is
2 3 4 5 6 7 8 9 10 11	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.  A. Right.  Q. Do you know how many of those women reporting dyspareunia actually had it before any kind of mesh device was implanted?  MR. GOSS: Objection. Form.  THE WITNESS: No, not without not without going back and reading each one.	2 3 4 5 6 7 8 9 10 11 12	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question; right?  Q. Well, it was, and I thought you said you couldn't come up with one, as you sit here.  A. Right. Then I decided to look at my report.  For example, on page 26, this is one of the issue reports that was determined
2 3 4 5 6 7 8 9 10 11 12 13	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.  A. Right. Q. Do you know how many of those women reporting dyspareunia actually had it before any kind of mesh device was implanted?  MR. GOSS: Objection. Form.  THE WITNESS: No, not without not without going back and reading each one.  BY MS. SUTHERLAND:	2 3 4 5 6 7 8 9 10 11 12 13	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question; right?  Q. Well, it was, and I thought you said you couldn't come up with one, as you sit here.  A. Right. Then I decided to look at my report.  For example, on page 26, this is one of the issue reports that was determined by Ethicon not to be reportable.
2 3 4 5 6 7 8 9 10 11 12 13 14	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.  A. Right.  Q. Do you know how many of those women reporting dyspareunia actually had it before any kind of mesh device was implanted?  MR. GOSS: Objection. Form.  THE WITNESS: No, not without not without going back and reading each one.  BY MS. SUTHERLAND:  Q. And sometimes it wouldn't be in	2 3 4 5 6 7 8 9 10 11 12 13 14	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question; right?  Q. Well, it was, and I thought you said you couldn't come up with one, as you sit here.  A. Right. Then I decided to look at my report.  For example, on page 26, this is one of the issue reports that was determined by Ethicon not to be reportable.  Q. Did you say 26 or 126?
2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.  A. Right.  Q. Do you know how many of those women reporting dyspareunia actually had it before any kind of mesh device was implanted?  MR. GOSS: Objection. Form.  THE WITNESS: No, not without not without going back and reading each one.  BY MS. SUTHERLAND:  Q. And sometimes it wouldn't be in there anyways; right?	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question; right?  Q. Well, it was, and I thought you said you couldn't come up with one, as you sit here.  A. Right. Then I decided to look at my report.  For example, on page 26, this is one of the issue reports that was determined by Ethicon not to be reportable.  Q. Did you say 26 or 126?  A. 126. Sorry.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.  A. Right. Q. Do you know how many of those women reporting dyspareunia actually had it before any kind of mesh device was implanted?  MR. GOSS: Objection. Form.  THE WITNESS: No, not without not without going back and reading each one.  BY MS. SUTHERLAND: Q. And sometimes it wouldn't be in there anyways; right? A. No, and that's why the manufacturer	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question; right?  Q. Well, it was, and I thought you said you couldn't come up with one, as you sit here.  A. Right. Then I decided to look at my report.  For example, on page 26, this is one of the issue reports that was determined by Ethicon not to be reportable.  Q. Did you say 26 or 126?  A. 126. Sorry.  Q. Got it.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.  A. Right.  Q. Do you know how many of those women reporting dyspareunia actually had it before any kind of mesh device was implanted?  MR. GOSS: Objection. Form.  THE WITNESS: No, not without not without going back and reading each one.  BY MS. SUTHERLAND:  Q. And sometimes it wouldn't be in there anyways; right?  A. No, and that's why the manufacturer has responsibility to investigate.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question; right?  Q. Well, it was, and I thought you said you couldn't come up with one, as you sit here.  A. Right. Then I decided to look at my report.  For example, on page 26, this is one of the issue reports that was determined by Ethicon not to be reportable.  Q. Did you say 26 or 126?  A. 126. Sorry.  Q. Got it.  A. And, for example, it says,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.  A. Right. Q. Do you know how many of those women reporting dyspareunia actually had it before any kind of mesh device was implanted?  MR. GOSS: Objection. Form.  THE WITNESS: No, not without not without going back and reading each one.  BY MS. SUTHERLAND: Q. And sometimes it wouldn't be in there anyways; right?  A. No, and that's why the manufacturer has responsibility to investigate. Q. And from your review, how often did	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question; right?  Q. Well, it was, and I thought you said you couldn't come up with one, as you sit here.  A. Right. Then I decided to look at my report.  For example, on page 26, this is one of the issue reports that was determined by Ethicon not to be reportable.  Q. Did you say 26 or 126?  A. 126. Sorry.  Q. Got it.  A. And, for example, it says, "Notably, it was speculation and my
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.  A. Right. Q. Do you know how many of those women reporting dyspareunia actually had it before any kind of mesh device was implanted?  MR. GOSS: Objection. Form.  THE WITNESS: No, not without not without going back and reading each one. BY MS. SUTHERLAND: Q. And sometimes it wouldn't be in there anyways; right?  A. No, and that's why the manufacturer has responsibility to investigate. Q. And from your review, how often did Ethicon attempt to follow up for reports?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question; right?  Q. Well, it was, and I thought you said you couldn't come up with one, as you sit here.  A. Right. Then I decided to look at my report.  For example, on page 26, this is one of the issue reports that was determined by Ethicon not to be reportable.  Q. Did you say 26 or 126?  A. 126. Sorry.  Q. Got it.  A. And, for example, it says, "Notably, it was speculation and my professional opinion for the medical
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q. All right. Do the MDR reports set out pre-existing conditions? Let me ask it as an example. For instance, I know some of your charts show reports of dyspareunia.  A. Right.  Q. Do you know how many of those women reporting dyspareunia actually had it before any kind of mesh device was implanted?  MR. GOSS: Objection. Form.  THE WITNESS: No, not without not without going back and reading each one.  BY MS. SUTHERLAND:  Q. And sometimes it wouldn't be in there anyways; right?  A. No, and that's why the manufacturer has responsibility to investigate.  Q. And from your review, how often did Ethicon attempt to follow up for reports?  A. My I'm checking my memory let me just double check. If you look on page 124 of the main report, I note that the majority of reports were initial reports	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. No. That wouldn't be there, but I was going to I was looking to see if I might be able to give you a specific example, which I thought was your question; right?  Q. Well, it was, and I thought you said you couldn't come up with one, as you sit here.  A. Right. Then I decided to look at my report.  For example, on page 26, this is one of the issue reports that was determined by Ethicon not to be reportable.  Q. Did you say 26 or 126?  A. 126. Sorry.  Q. Got it.  A. And, for example, it says, "Notably, it was speculation and my professional opinion for the medical reviewer to conclude that the erosion would not worsen and/or require treatment, and I reviewed no evidence of follow up by Ethicon to determine outcome of the erosion. The

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Page 270 So that's an example of where they should have followed up to see if there were any consequences to really understand the safety profile of the product and feed that risk information back into the risk analysis, which should always be ongoing during the development -- during the marketing of a product, post-marketing as well as pre-marketing, to assure that 10 there's a favorable benefit to risk ratio. Q. As far as attempts at follow up, 12 did you come up with any sort of average of the number of times that Ethicon attempts to 13 14

- follow up to get information?
- A. As I sit here today, I don't recall having come up with a particular number because the point, again, is not --
- Q. Well, I think you answered my question.
- A. -- not the number. It's the fact that they have an obligation to follow these up to understand the safety profile of their product and report as appropriate.
- 24 Q. I'm going to move to strike everything after you didn't come up with a 25

information necessary to make that 1 2 determination.

> Q. Yeah. My question is: In order to be a reportable event to FDA, do you, number one, have to have a product identified?

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Page 273

MR. GOSS: Objection. Form. THE WITNESS: Generally

8 speaking, I would say, yes.

BY MS. SUTHERLAND:

Q. I was going to say --

A. But -- well, no. But I'm

hesitating because it's not a black and white necessarily question because you can

13 get a report that says, "We used an Ethicon 14

product, and we implanted this device, and 15 the woman in whom we implanted it is 16

continuing to have chronic infection and 17

18 erosion," and they may not state what the device is. 19

20 So you have to follow that up. You 21 need to make sure it's your product and

through investigation, try and -- you have 22

to make a due diligence effort, a valid due 23

24 diligence effort, and Ethicon has its own

standard operating procedures. 25

Page 271

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They know what they must do to

2 follow it up to determine what product it is 3 and to find out more about the information

to determine whether it's reportable,

5 whether there's a follow-up report required, 6

et cetera.

7 And the whole basis of that, again, 8 is to always substantiate that a product is

9 meeting the essential principles of safety 10 and performance. If it's not Ethicon's

product, and they get a report for some 11

other manufacturer's mesh, they don't have 12

to submit an MDR report, but they are 13 supposed to send a letter to the FDA letting 14

15 the FDA know about it so that that

information doesn't get lost. 16

Again, all in the interest of 17

18 patient safety. But, generally speaking, they need to -- you know, they could also 19

20 make a report that says this -- there should

always be a tendency in the global standard. 21 There should always be a tendency in doubt, 22

when you're in doubt, to report rather than 23

24 not to report. 25

So if they're unable to determine

specific number.

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Going back to MDR reports, are there certain requirements that have to be present in order for a reported event to be reportable to FDA?

A. Yes.

Q. Okay. And what are those?

A. It has to be a serious or

life-threatening event where there is a reasonable association with the device, and as well for malfunctions, if that malfunction were to recur, that a serious or life-threatening event could result.

Q. Okay. Is there also a similar requirement for devices like there is for drugs that a reporter has to be identified, an event, a patient, and a product?

A. I'm not sure exactly what you're asking because a report from any source -obviously, there has to be --

Q. There's got to be a reporter.

A. There's got to be a reporter.

Q. Right.

A. And information that you can follow 24

25 up to determine whether or not -- to get the

Page 274 Page 276 which particular product it was, but it's 1 I'm going to start with the Global 2 fairly substantiated that it was an Ethicon 2 Harmonization Task Force issues. 3 3 product, and it was a sling, but they can't A. Okay. 4 determine if it was a TVT or a TVT-O, they 4 O. Now, am I correct that the Global 5 5 could still report that to the FDA and say Harmonization Task Force was sort of formed unable to determine which sling but 6 in 1992? 6 7 information confirms that it's an Ethicon 7 A. Yes. 8 8 Q. All right. And as I understand it, 9 Q. And did you, in fact, see where 9 there were members from different countries, 10 Ethicon did that very thing? 10 approximately five --11 A. I don't recall a specific example 11 A. Yes. 12 of that, as I sit here today. 12 Q. -- for sort of the task force. Q. Are you saying it didn't happen, or A. Countries or regions. 13 13 14 you just don't recall? 14 O. All right. And would that be the European Union? 15 MR. GOSS: Objection. Form. 15 THE WITNESS: No. I just don't A. Yes. 16 16 17 recall, as I sit here today. 17 O. The U.S.? 18 BY MS. SUTHERLAND: 18 A. Yes. Q. All right. Did you look at the 19 O. Canada? 19 20 reported events to see whether or not 20 A. Yes. Ethicon took even a more conservative 21 Q. Japan? 21 22 approach and reported something that you 22 A. Yes. 23 wouldn't have reported? 23 O. And France? 24 MR. GOSS: Objection. Form. 24 A. Oh, I think it was Australia. 25 BY MS. SUTHERLAND: 25 Q. Oh, they met -- yeah, I think Page 275 Page 277 Q. Did you perform that review? 1 you're right. Australia. 1 2 2 A. As you've asked the question, as I Was the purpose of the GHTF to come 3 understand it, I didn't perform that review. 3 up with some documents that harmonized 4 Q. Okay. 4 regulatory processes across the countries? 5 A. As I mentioned, there should always 5 A. Yes. To provide a global model -be a tendency, if there's any question, to 6 6 Q. All right. 7 report rather than not to report. 7 A. -- for development of medical 8 Q. Okay. Move to strike everything 8 devices with the intent of patient safety 9 after "I did not perform that review." 9 and being able to bring important new 10 Is there a requirement for some 10 technologies to the market in a safe, cost sort of identifier of a patient in order for effective, efficient manner. 11 11 12 an adverse event to be reportable, meaning 12 O. And in that effort to reach that the gender of the patient, the age, goal, am I correct that certain guidances 13 13 something like that? were promulgated by the GHTF? 14 14 15 A. The age, no. The gender, not 15 A. Yes, that's correct. necessarily. If it's a device that can be Q. All right. Was the intent then 16 16 used in both sexes, you provide -- again, that those guidances would then be adopted 17 17 18 that's why you investigate. You try and 18 by the regulatory agencies of those obtain as much information as necessary, and different countries or regions? 19 19 then you make an appropriate judgment as to 20 A. Yes. And even beyond those 20 whether or not it needs to be reported. countries and regions but would even be more 21 21 22 O. All right. Let's switch gears 22 global and other countries that didn't have again, and I'm going to walk you through as well -- the countries and regions that 23 23 some particular aspects of your report that were involved had more established 24 24 25 we haven't already covered, part of which 25 regulatory framework for medical devices,

Page 278 Page 280 and so for countries and regions that didn't 1 device industry group in the United States? 2 have as well developed regulatory framework, 2 A. I would say, yes. this would also -- the GHTF guidance 3 3 Q. All right. 4 documents would also help those countries to 4 A. That's my understanding. 5 5 be able to have a framework for development Q. Now, under this first section 6 of safe and effective medical devices. 6 there, Global Harmonization Task Force of 7 Q. And all of this was for the 7 1992, it sets out sort of what we've already 8 8 regulatory processes in the different talked about that in September 1992, senior 9 countries to be harmonized so that, for 9 regulate officials and industry reps from 10 instance, a manufacturer in one country knew 10 those different areas met in France; 11 what was required for clearance in another 11 correct? 12 country across the globe. 12 A. Right. A. It was more than that. It 13 13 Q. And that was for the purpose of exploring "the formation of a global 14 certainly was for that purpose, but it was 14 also to establish the standards for testing, partnership chartered to harmonize medical 15 15 for labeling, the guidances for risk device regulatory practices worldwide"; is 16 16 management, quality system for manufacturers 17 17 that right? 18 because the Global Harmonization Task Force 18 A. That's what this says, yes. 19 was a partnership between the industry and 19 Q. Is that not right? 20 regulators so that there was equal 20 A. No. I said that was right, but, I representation across industry and 21 think, it also provides documentation for 21 22 regulators for GHTF for its approximately 22 how to develop a medical device to guide manufacturers and how the appropriate 23 20-year history. 23 24 Q. Now, study groups were created 24 methods -- the appropriate types of testing, under the umbrella of the GHTF; correct? labeling requirements, risk assessment, 25 25 Page 279 Page 281 A. That's correct. 1 quality system, it sets out the standards 1 2 O. And there were five of them? 2 for medical device companies to follow in 3 A. That's correct. 3 being able to bring safe, effective, quality 4 Q. And those leaders of those study 4 products to market. 5 groups were all regulators, weren't they? 5 Q. Now, those guidances were based on 6 A. I don't know specifically if the 6 regulations already in place in the 7 leaders were all regulators. The study 7 different countries that were members of groups were compromised of both regulators 8 8 GHTF, weren't they? 9 and -- both regulators and industry 9 A. They utilized those, yes. But, representatives. 10 again, it's a representation of medical 10 Q. All right. I'm going to hand you device industry, AdvaMed participated. If I 11 11 recall correctly, AdvaMed was on the 12 what I've marked as Exhibit Number 12. 12 steering committee, and AdvaMed 13 (Exhibit Number 12 was 13 marked for identification.) participated, representatives from companies 14 14 15 BY MS. SUTHERLAND: 15 that were part of AdvaMed participated, and Q. This is a printout of AdvaMed's then the regulators. 16 16 Q. Now, the third paragraph in there 40th anniversary discussing the GHTF. 17 17 18 Now, have you ever seen this 18 said that "The mission of GHTF was to encourage the convergence in regulatory 19 document before? 19 20 A. I don't recall, as I sit here practices related to ensuring the safety, 20 21 today, having seen this particular one. 21 effectiveness, and quality of medical Q. All right. What is AdvaMed? 22 22 devices." A. It's an industry organization that Do you agree with that statement? 23 23 represents medical device companies. A. Yes, as well as the rest, which is 24 24 25 Q. Okay. Is it the largest medical 25 promoting technological innovation which has

Page 282 Page 284 1 to do with companies --1 Q. And that pilot program that you're 2 Q. Right. 2 talking about, is that set out in some sort 3 A. -- and facilitating international 3 of FDA document? 4 4 A. Yes. It's on the -- you can find trade. 5 5 Q. Correct. And then it goes on and it on the FDA website. says, "This important task was accomplished 6 6 Q. All right. Other than that pilot 7 through the development and dissemination of 7 program that you're talking about on 8 harmonized guidance documents on regulatory 8 auditing, did FDA adopt any other guidance 9 practices." 9 put out by GHTF? A. If you'll -- Tim Ulatowski, who is 10 Do you agree with that statement? 10 11 A. Yes, but it's more than regulatory 11 your expert in these cases, actually, back 12 practices because there are documents that 12 around --13 talk about clinical evaluation, what 13 Q. Well, you note something from him clinical evidence means, all of the same from 2009 in your report. 14 14 kind of -- it's not just for regulators. A. I said they were becoming -- that 15 15 This information is intended to be companies should be aware of them, that they 16 16 used by companies developing products in were becoming the standard. And --17 17 18 order to take the appropriate steps and have 18 Q. And my question is a little bit a model to follow to produce safe and 19 different. 19 20 effective and high-quality products, quality 20 MR. GOSS: Wait, wait, wait, product, to bring to the market in their 21 wait. Slow down a little bit. 21 22 various regions or countries. 22 BY MS. SUTHERLAND: Q. It goes on to say, "These critical 23 23 Q. My question was specifically on 24 documents" -- meaning these guidances --24 whether you can tell me which, if any, "which were developed by the five different 25 25 guidance put out by GHTF has been adopted by Page 283 Page 285 study groups were then to be implemented by 1 FDA. 1 2 member national regulatory authorities to 2 A. I would have to check the status of further the goal of harmonization." 3 it. I know that there was also a pilot 3 program where the FDA was encouraging the 4 Now, was that -- is that your 5 understanding of what was to be accomplished 5 use of the STED document for submission of through the GHTF? medical device applications. I would have 6 6 to check the status of that, at this point 7 7 A. Yes. 8 Q. Okay. 8 in time. 9 A. Yes. 9 Many of the GHTF documents are very 10 Q. Which GHTF guidances were adopted 10 reflective already of the FDA regulations because obviously FDA was a major 11 by FDA? 11 12 12 A. There are -- there are a number of participant. 13 those like, for example, the auditing one. 13 Q. Now, is this the pilot program on FDA is currently using a GHTF auditing the STED that you're talking about? 14 14 15 guidance in cooperation with, I believe, 15 Let me mark that as 13. it's Japan and maybe Canada -- I'd have to (Exhibit Number 13 was 16 16 check back to refresh my memory -- to look 17 17 marked for identification.) 18 at an auditing model to audit medical device 18 THE WITNESS: Yes. companies so that they don't have to be 19 19 BY MS. SUTHERLAND: 20 audited by multiple countries and that by 20 Q. Okay. Now, I'm not aware of that working together through GHTF, the GHTF 21 21 actually being implemented past 2005. Are 22 model for auditing, that they all accept 22 vou? that whatever the audit is, that they will 23 23 A. Not without checking, I don't 24 accept the -- it's a pilot program 24 recall. 25 currently. 25 Q. All right. So now other than the

	337			
	Page 286		ı	Page 288
1	two pilot programs that you've mentioned to	1	And I just had a quick question.	
2	me, are you aware of any guidance from GHTF	2	You note there about the Medscand payments	
3	that FDA has adopted?	3	of 400,000	
4	A. As I sit here today, I don't recall	4	A. Yes.	
5	without going back and looking at all of	5	Q and that are you offering an	
6	them	6	opinion that that financial information	
7	Q. Okay.	7	should have been disclosed in the TVT	
8	A and checking. What I can tell	8	510(k)?	
9	you in answer to your question is that the	9	A. Yes.	
10	reason for I was able to find some	10	Q. All right. And am I correct,	
11	further documentation. The reason for	11	though, that the regulation requiring that	
12	disbanding GHTF and transitioning GHTF's	12	type of disclosure actually wasn't finalized	
13	work to IMDRF was specifically for that	13	until after the submission of the TVT	
14	purpose. That incorporation of these	14	510(k)?	
15	guidance documents into the regulatory	15	A. That is correct.	
16	framework to the regulations had been slower	16	Q. All right. Let's move on to	
17	than had been hoped and so	17	page 54. And as I review your report, at	
18	Q. In fact, not at all; right?	18	least for this specific one, I understood	
19	A. Well, in some places, I don't think	19	you to be saying that there were two	
20	that's true. They are in the U.S.	20	cytotoxicity tests that should have been	
21	Q. In the U.S., not at all; right?	21	provided to FDA?	
22	A. In the U.S., but in other places,	22	A. Yes.	
23	they were being incorporated, but the	23	Q. All right. Now	
24	incorporation was slower than anticipated,	24	A. Or should have and should have	
25	and so the regulators decided that they	25	been also followed up further to understand	
	and so the regulators decided that they	23	been also rollowed up rartiel to understand	
	Page 287			Page 289
1	could make that happen after the 20 years of	1	why they were getting positive cytotoxicity	age 203
2	GHTF and with the global framework that had	2	tests.	
3	been developed, that now if the regulators	3	Q. Okay. I got you.	
4	were to take the ball, if you will, that	4	But what I'm going for here is what	
5	they could work more effectively to get the	5	are you going to tell a jury that Ethicon	
6	GHTF guidance documents and any new	6	should have given to FDA but didn't, and I	
7	documents that IMDRF would develop	7	know you and I have talked about the MDRs.	
8	incorporated into the regulations of their	8	We've now talked about these two	
9	respective areas.	9	cytotoxicity tests.	
10	Q. All right. And IMDRF doesn't have	10	A. Right.	
11	industry representatives right?	11	Q. Now, is there other specific	
12	A. No. It's all regulators.	12	documentation that you're going to say	
13	Q. All regulators. Okay.	13	Ethicon should have given to FDA but didn't	
14	MS. SUTHERLAND: How much time	14	with respect to the TVT-O?	
15	do we have?	15	MR. GOSS: Objection. Form.	
16	THE VIDEOGRAPHER: About	16	THE WITNESS: For example, the	
17	you're at 5 hours 24 minutes.	17	issues with fraying and particle loss of	
18	MS. SUTHERLAND: Let's keep	18	the mesh, the mechanically cut mesh, the	
19	going.	19	roping, the curling.	
20	BY MS. SUTHERLAND:	20	BY MS. SUTHERLAND:	
21	Q. Flip over to page 42.	21	Q. Yeah. I'm asking about can you	
22	A. Of my report?	22	name for me a specific document that you're	
23	Q. Of your report, yes, ma'am.	23	talking about that you say Ethicon should	
24	A. 42?	24	have give to FDA but didn't?	
			: <del>: -: -: -:</del>	
25	Q. Yes, ma'am.	25	A. Well, there are a number of	

Page 290 Page 292 Q. Those 58 reports of fraying, were 1 documents related to the fraying, the 1 2 particle loss. 2 they reported to FDA's MDRs? 3 3 Q. Can you tell -- I mean, I need to A. To the best of my recollection, 4 know if you're going to say, "Ethicon should 4 there may have been some but not all. I'd 5 have to go back and check my records. have given this document to FDA," I want to 5 6 know what this document is. 6 That's to the best of my recollection. 7 A. Well, for example, if I'm recalling 7 Q. Okay. 8 8 correctly, Gene Kammerer's, the engineer, A. And let's see -- yes. I know for 9 lead engineer, Gene Kammerer -- there's a --9 sure that in the discussion of malfunctions 10 I believe it's a PowerPoint presentation 10 in the back of my report. Definitely 11 where they're actually pictures of the mesh 11 there -- there, for example, eight reports 12 and the particle loss and how the structure 12 of the mesh fraying, unraveling, and on fragments falling off, the tape becoming 13 is lost, the mesh structure is lost, and the 13 word "degradation" was used separate from particles. So there were definitely reports 14 14 degradation once implanted, but degradation that were not submitted to FDA. 15 15 of the structure of the mesh and the 16 16 Q. Okay. But there were actually some particle loss and the fact that there was no reports of fraying that were reported to FDA 17 17 18 testing to determine whether or not those 18 by Ethicon: right? 19 particles might have any impact for safety 19 A. I'd have to go back and double 20 and effectiveness. 20 check. 21 The narrowing -- the narrowing and 21 Q. You don't know that sitting here 22 the roping and the curling of the mesh, the 22 today? fact that that was considered, and it's been 23 23 A. There are many MDR reports. To the testified to by Ethicon employees that that 24 best of my recollection as I sit here today, 24 25 was a product defect. 25 there were some, but I'd have to just verify Page 291 Page 293 Q. Okay. Now, you told me about a 1 my memory. 1 2 2 PowerPoint --Q. Okay. 3 3 A. I believe it was a PowerPoint. A. And that's very important because 4 Q. -- by Mr. Kammerer. 4 that goes not only to determining safety and 5 A. Yes. 5 effectiveness, that's an important 6 6 consideration for FDA's determination of Q. All right. What other document are 7 7 you going to say should have been given to substantial equivalence, and that 8 information was known to Ethicon and not 8 FDA but wasn't? 9 A. At that point in time --9 provided to the FDA. Q. And what point in time are we 10 Q. Move to strike everything after 10 talking about? your first clause where, I think, you said 11 11 A. Submission of 510(k). that you thought some were reported to FDA, 12 12 13 O. Okay. 13 but you'd have to confirm. A. Some of the documents I have Let me get you to move to page 107 14 14 15 referenced, I don't have years indicated in 15 of your report. my reference. So without checking back the A. Okay. 16 16 document, I can't say whether it had the O. And if we're flipping through 17 17 18 information available at the time of 18 there, by my count, you pull out five pieces submission or not, but I do know, for of promotional material on pages 107 to 114. 19 19 example, that by November, 2003, that they 20 Is that right? 20 21 had -- Ethicon had at least had received a 21 A. I'll double check. Yes. 22 total of 58 complaints of fraving, and they 22 O. All right. Now, are those five also had information from their preceptors pieces of promotional materials what you're 23 23 24 about denaturing and linting being a 24 relying on to support your opinion number 4? 25 concern, leaving particles in patients. 25 A. Yes.

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	Page 294			Page 296
1	Q. Now, let's go back and look at	1	disclosed.	
2	on page 107, the first piece that you have	2	Q. And then move to page 110 of your	
3	there.	3	report, and there's your second marketing	
4	A. Okay.	4	piece.	
5	Q. All right. First of all, that	5	A. Yes.	
6	one's entitled "Only Gynecare TVT Has	6	Q. All right. Now, do you have any	
7	Long-Term Results You Can See blah, blah,	7	information that Dr. Reyes saw this	
8	blah "and Believe."	8	particular marketing piece?	
9	A. Right.	9	MS. VERBEEK: Object to form.	
10	Q. All right. Now, do you have any	10	MR. GOSS: Objection. Form.	
11	information that the implanter in the	11	THE WITNESS: To the best of my	
12	Jennifer Ramirez case, Dr. Reyes, saw that	12	recollection as I sit here today, I	
13	piece?	13	don't recall that he testified as to	
14	•	14		
	MR. GOSS: Objection. Form.		having seen this particular piece.	
15	MS. VERBEEK: Same objection.	15	BY MS. SUTHERLAND:	
16	THE WITNESS: I don't recall	16	Q. All right. Now, did you perform	
17	that he testified about this	17	any kind of survey to determine how	
18	BY MS. SUTHERLAND:	18	physicians perceived this particular	
19	Q. Okay.	19	marketing piece?	
20	A as I sit here today.	20	MR. GOSS: Objection. Form.	
21	Q. All right. Have you done any kind	21	MS. VERBEEK: Objection. Form.	
22	of survey of surgeons to determine what	22	THE WITNESS: My assessment was	
23	their perception is of this particular	23	based on the requirements for what is	
24	piece, number 1, on your report, page 107?	24	supposed to be in promotional labeling.	
25	A. No. My evaluation was based on	25	I did not perform a survey.	
	Page 295	,	DVAMS SUTUEDIAND	Page 297
1	what the requirements are for promotional	1	BY MS. SUTHERLAND:	Page 297
2	what the requirements are for promotional labeling.	2	Q. And with respect to you note,	Page 297
2 3	what the requirements are for promotional labeling. Q. Now, you discuss there in that	2	Q. And with respect to you note, again, the financial conflict of Professor	Page 297
2 3 4	what the requirements are for promotional labeling. Q. Now, you discuss there in that paragraph that the financial conflicts of	2 3 4	Q. And with respect to you note, again, the financial conflict of Professor Ulmsten and Nilsson; right?	Page 297
2 3 4 5	what the requirements are for promotional labeling. Q. Now, you discuss there in that paragraph that the financial conflicts of Professor Ulmsten and Professor Nilsson were	2 3 4 5	Q. And with respect to you note, again, the financial conflict of Professor Ulmsten and Nilsson; right? A. Yes.	Page 297
2 3 4 5 6	what the requirements are for promotional labeling.  Q. Now, you discuss there in that paragraph that the financial conflicts of Professor Ulmsten and Professor Nilsson were not disclosed; correct?	2 3 4 5 6	Q. And with respect to you note, again, the financial conflict of Professor Ulmsten and Nilsson; right? A. Yes. Q. And then you also pull in Professor	Page 297
2 3 4 5 6 7	what the requirements are for promotional labeling.  Q. Now, you discuss there in that paragraph that the financial conflicts of Professor Ulmsten and Professor Nilsson were not disclosed; correct?  A. That's correct.	2 3 4 5	Q. And with respect to you note, again, the financial conflict of Professor Ulmsten and Nilsson; right? A. Yes. Q. And then you also pull in Professor de Leval; correct? Do you see that last	Page 297
2 3 4 5 6 7 8	what the requirements are for promotional labeling.  Q. Now, you discuss there in that paragraph that the financial conflicts of Professor Ulmsten and Professor Nilsson were not disclosed; correct?  A. That's correct.  Q. All right. Now, are you opining	2 3 4 5 6 7 8	Q. And with respect to you note, again, the financial conflict of Professor Ulmsten and Nilsson; right? A. Yes. Q. And then you also pull in Professor de Leval; correct? Do you see that last sentence there on the first paragraph?	Page 297
2 3 4 5 6 7 8	what the requirements are for promotional labeling.  Q. Now, you discuss there in that paragraph that the financial conflicts of Professor Ulmsten and Professor Nilsson were not disclosed; correct?  A. That's correct.  Q. All right. Now, are you opining that Professor Ulmsten or Professor Nilsson	2 3 4 5 6 7 8 9	Q. And with respect to you note, again, the financial conflict of Professor Ulmsten and Nilsson; right? A. Yes. Q. And then you also pull in Professor de Leval; correct? Do you see that last sentence there on the first paragraph? A. Yes, I do.	Page 297
2 3 4 5 6 7 8 9	what the requirements are for promotional labeling.  Q. Now, you discuss there in that paragraph that the financial conflicts of Professor Ulmsten and Professor Nilsson were not disclosed; correct?  A. That's correct.  Q. All right. Now, are you opining that Professor Ulmsten or Professor Nilsson manipulated their data to make it	2 3 4 5 6 7 8 9 10	Q. And with respect to you note, again, the financial conflict of Professor Ulmsten and Nilsson; right? A. Yes. Q. And then you also pull in Professor de Leval; correct? Do you see that last sentence there on the first paragraph? A. Yes, I do. Q. Okay. Now, are you opining that	Page 297
2 3 4 5 6 7 8 9 10	what the requirements are for promotional labeling.  Q. Now, you discuss there in that paragraph that the financial conflicts of Professor Ulmsten and Professor Nilsson were not disclosed; correct?  A. That's correct.  Q. All right. Now, are you opining that Professor Ulmsten or Professor Nilsson manipulated their data to make it inaccurate?	2 3 4 5 6 7 8 9 10 11	Q. And with respect to you note, again, the financial conflict of Professor Ulmsten and Nilsson; right? A. Yes. Q. And then you also pull in Professor de Leval; correct? Do you see that last sentence there on the first paragraph? A. Yes, I do. Q. Okay. Now, are you opining that Professor de Leval manipulated his data to	Page 297
2 3 4 5 6 7 8 9 10 11 12	what the requirements are for promotional labeling.  Q. Now, you discuss there in that paragraph that the financial conflicts of Professor Ulmsten and Professor Nilsson were not disclosed; correct?  A. That's correct.  Q. All right. Now, are you opining that Professor Ulmsten or Professor Nilsson manipulated their data to make it inaccurate?  A. I'm not opining that. What I'm	2 3 4 5 6 7 8 9 10 11 12	Q. And with respect to you note, again, the financial conflict of Professor Ulmsten and Nilsson; right? A. Yes. Q. And then you also pull in Professor de Leval; correct? Do you see that last sentence there on the first paragraph? A. Yes, I do. Q. Okay. Now, are you opining that Professor de Leval manipulated his data to make it inaccurate?	Page 297
2 3 4 5 6 7 8 9 10 11 12 13	what the requirements are for promotional labeling.  Q. Now, you discuss there in that paragraph that the financial conflicts of Professor Ulmsten and Professor Nilsson were not disclosed; correct?  A. That's correct.  Q. All right. Now, are you opining that Professor Ulmsten or Professor Nilsson manipulated their data to make it inaccurate?  A. I'm not opining that. What I'm opining is that there is any time there	2 3 4 5 6 7 8 9 10 11 12 13	Q. And with respect to you note, again, the financial conflict of Professor Ulmsten and Nilsson; right?  A. Yes. Q. And then you also pull in Professor de Leval; correct? Do you see that last sentence there on the first paragraph?  A. Yes, I do. Q. Okay. Now, are you opining that Professor de Leval manipulated his data to make it inaccurate?  A. No. I'm, again, opining that	Page 297
2 3 4 5 6 7 8 9 10 11 12 13 14	what the requirements are for promotional labeling.  Q. Now, you discuss there in that paragraph that the financial conflicts of Professor Ulmsten and Professor Nilsson were not disclosed; correct?  A. That's correct.  Q. All right. Now, are you opining that Professor Ulmsten or Professor Nilsson manipulated their data to make it inaccurate?  A. I'm not opining that. What I'm opining is that there is any time there is a financial arrangement that could impact	2 3 4 5 6 7 8 9 10 11 12 13 14	Q. And with respect to you note, again, the financial conflict of Professor Ulmsten and Nilsson; right? A. Yes. Q. And then you also pull in Professor de Leval; correct? Do you see that last sentence there on the first paragraph? A. Yes, I do. Q. Okay. Now, are you opining that Professor de Leval manipulated his data to make it inaccurate? A. No. I'm, again, opining that there's a potential for bias and because of	Page 297
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	what the requirements are for promotional labeling.  Q. Now, you discuss there in that paragraph that the financial conflicts of Professor Ulmsten and Professor Nilsson were not disclosed; correct?  A. That's correct.  Q. All right. Now, are you opining that Professor Ulmsten or Professor Nilsson manipulated their data to make it inaccurate?  A. I'm not opining that. What I'm opining is that there is any time there is a financial arrangement that could impact one's assessment of data and particularly where positive data is required in order for	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q. And with respect to you note, again, the financial conflict of Professor Ulmsten and Nilsson; right? A. Yes. Q. And then you also pull in Professor de Leval; correct? Do you see that last sentence there on the first paragraph? A. Yes, I do. Q. Okay. Now, are you opining that Professor de Leval manipulated his data to make it inaccurate? A. No. I'm, again, opining that there's a potential for bias and because of that potential for bias, it is the standard, it's a requirement from a regulatory	Page 297
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			1		
	•	Page 298			Page 300
1	after "no."		1	survey.	
2	If you turn to page 112 of your		2	BY MS. SUTHERLAND:	
3	report, and that gets us to your third		3	Q. All right. And for the last piece	
4	marketing piece?		4	on page 5, did you perform any kind of	
5	A. Yes.		5	survey to determine physicians perception of	
6	Q. And this one is dated 2010?		6	that fifth marketing piece?	
7	A. Yes.		7	MS. VERBEEK: Object to form.	
8	Q. All right. Now, do you have any		8	THE WITNESS: With the same	
9	information that Dr. Reyes saw this		9	comments as for the prior promotional	
10	marketing piece?		10	labeling pieces, no.	
11	MR. GOSS: Objection. Form.		11	BY MS. SUTHERLAND:	
12	THE WITNESS: I don't recall.		12	Q. All right. And do you have any	
13	MS. VERBEEK: Objection. Form.		13	information that Dr. Reyes saw this	
14	THE WITNESS: I don't recall		14	particular piece?	
15	having seen testimony that as regards		15	<ul> <li>A. I don't recall any specific</li> </ul>	
16	his having seen this piece.		16	information in his testimony as regards to	
17	BY MS. SUTHERLAND:		17	this piece, as I sit here today.	
18	Q. Okay. Did you perform any kind of		18	Q. Under your opinion there, the	
19	survey to determine physicians perceptions		19	second sentence you note, "Labelling can be	
20	of this particular marketing piece on		20	deemed by FDA to be misleading and in	
21	page 112?		21	violation of FDA requirements if it proves	
22	MR. GOSS: Objection. Form.		22	deceptive to the customer by creating or	
23	MS. VERBEEK: Object to form.		23	leading to a false impression in the mind of	
24	THE WITNESS: With the same		24	the reader."	
25	comment as I made for the prior two, no,		25	Did I read that correctly?	
		Page 299			Page 301
1	I did not.	. age 255	1	A. Yes, you did.	1 ugc 301
2	BY MS. SUTHERLAND:		2	Q. All right. Now, number one, has	
3	Q. Okay. Turn to page 114. And up at		3	FDA ever issued any kind of documentation	
4	the top, we have your fourth marketing		4	for these five pieces saying that they were	
5	piece.		5	misleading or in violation of any FDA	
6	A. Yes.		6	requirement?	
7	Q. And, again, do you have any		7	A. Not that I've seen, but they were	
8	information that Dr. Reyes saw this			7 ii 1100 diac 1 10 booily bac die, 1101	
ı	information that Dr. Neyes saw this		8	not just submitted to FDA, as far as I know.	
9	particular marketing piece?		8 9		t.
	particular marketing piece?  MS. VERBEEK: Object to form.			not just submitted to FDA, as far as I know.	t.
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Page 302 Page 304 do any kind of survey to determine if any 1 1 carcinogenic. If I'm asked about that, I 2 physician got a false impression in their 2 would opine that there have been cases now mind after reading any of these five pieces; 3 3 that have been reported where polypropylene 4 4 as well as other polyester meshes and TVTs correct? 5 MR. GOSS: Objection. Form. 5 have been found in association with tumors 6 THE WITNESS: Based on my 6 and that the authors of those reports have 7 experience --7 not concluded that the mesh was the cause of 8 BY MS. SUTHERLAND: 8 the tumor but that it may have been a 9 Q. Is that a yes or a no? 9 contributing factor. 10 A. I can't give you just a yes or no. 10 Q. And are those case reports, the, I think, four or five that are set out in your 11 Q. Well, you didn't do a survey; 11 12 12 report? right? 13 A. I have, based on years of 13 A. Yes. experience and knowledge and reviewing, a 14 14 O. Are there any other pieces of number of warning letters about what should medical literature that you've looked at 15 15 be in promotional labeling and what should addressing whether or not mesh is 16 16 not as well as correspondence between carcinogenic? 17 17 18 companies who have submitted labeling of 18 MR. GOSS: Objection. Form. 19 this type and FDA correspondence and based 19 THE WITNESS: There is, as 20 on what the requirements are for what's 20 discussed in my report, in one of the supposed to be included, I made my 21 points I said should have been in the 21 22 assessment based on that and not a survey 22 warnings that there were rat sarcomas 23 because there's a certain standard that must 23 that were identified in the material 24 be met, and I made my assessment, and I've 24 safety data sheet with implantation. given the rationale for each piece as to BY MS. SUTHERLAND: 25 25 Page 303 Page 305 where it was false and misleading. 1 Q. I should have specified. I'm 1 2 And I made my assessment based on 2 asking about medical literature. Did you 3 what the requirements are for this type of 3 look at any other medical literature that addresses an issue of whether or not mesh is 4 labeling. 4 5 Q. All right. So in order to reach 5 associated with cancer other than what 6 this opinion -- essentially, we have your 6 you've got in your report? 7 opinion that under the FDA regs, it would 7 A. I certainly have -- I can't give 8 create or lead to a false impression in the you a specific -- I know I have looked at 8 solid state tumors and mesh and various --9 mind of a physician; correct? 9 10 A. My opinion based on many years of 10 I've looked into that. I can't give you a experience. specific document. I have done some 11 11 12 O. What we don't have is you even 12 research on it. I can't give you a specific document that I recall, as I sit here today. 13 talking to a single physician to confirm 13 your opinion; correct? 14 14 Q. All right. 15 MR. GOSS: Objection. Form. 15 A. Those case reports are important MS. VERBEEK: Object to form. because of the information that they 16 16 THE WITNESS: I have not talked 17 present, and it needs to be considered and 17 18 to a single physician. I based it on 18 for long-term implants, testing for -- and the requirements for this type of that goes into the testing for long-term 19 19 20 labeling and given the rationale for it, 20 inflammation, long-term infection. These are -- this is one of the 21 for my opinions. 21 22 BY MS. SUTHERLAND: 22 reasons, for example, for doing further Q. Do you intend to opine that Prolene testing, for having a registry. Without 23 23 having the appropriate follow up of these 24 mesh is carcinogenic? 24 25 A. I don't intend to opine that it's 25 patients, making such an association is

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	Page 306			Page 308
1	difficult. It cannot be done actually.	1	THE WITNESS: If she does, I	. ago ooo
2	Q. All right. I'm going to move to	2	have not seen any information with	
3	strike everything after your first clause.	3	regard to that.	
	Would you agree with me that	4	BY MS. SUTHERLAND:	
4	, ,	_		- 1
5	TVT-O the mesh in TVT-O is Prolene mesh.	5	Q. Okay. All right.	- 1
6	A. Yes.	6	A. I hope she doesn't.	- 1
7	Q. All right. And would you agree	7	Q. I hope she doesn't either.	- 1
8	with me that Prolene mesh has been used in	8	MS. SUTHERLAND: Let's go off for a	- 1
9	the body since the 1970s?	9	few minutes. I think I've got maybe ten	- 1
10	MR. GOSS: Objection. Form.	10	minutes. Let me make sure I've covered	- 1
11	BY MS. SUTHERLAND:	11	everything.	- 1
12	Q. You know it was a preeminent	12	MR. GOSS: Are you going to	- 1
13	device; right?	13	leave your co-defendant any time in the	- 1
14	THE WITNESS: Yes, I do.	14	six hours?	- 1
15	MR. GOSS: Objection. Form.	15	MS. SUTHERLAND: I didn't know	- 1
16	THE WITNESS: Yes, I agree with	16	I needed to.	- 1
17	that, but there's more to be considered	17	MS. VERBEEK: You probably	- 1
18	than just that fact.	18	don't. You've worn me out.	- 1
19	BY MS. SUTHERLAND:	19	MS. SUTHERLAND: I've worn	- 1
20	Q. Okay. Well, my question is do you	20	myself out.	- 1
		21	•	- 1
21	know, or do you not know that Prolene mesh		THE VIDEOGRAPHER: Going off?	- 1
22	has been used in the body since the 1970s?	22	MS. SUTHERLAND: Yes.	- 1
23	MR. GOSS: Objection. Form.	23	THE VIDEOGRAPHER: With the	- 1
24	THE WITNESS: Yes, I know that.	24	approval of counsel, going off the	- 1
25	BY MS. SUTHERLAND:	25	record. The time is approximately	- 1
	Page 307		4.07	Page 309
1	Q. Okay. Now, in the in 40 some-odd	1	4:37 p.m.	Page 309
2	Q. Okay. Now, in the in 40 some-odd years that Prolene mesh has been used in the	2	(Recess taken from	Page 309
2	Q. Okay. Now, in the in 40 some-odd years that Prolene mesh has been used in the body, is there a single case report where a	2	(Recess taken from 4:37 p.m. to 4:43 p.m.)	Page 309
2 3 4	Q. Okay. Now, in the in 40 some-odd years that Prolene mesh has been used in the body, is there a single case report where a doctor attributed cancer to Prolene mesh?	2 3 4	(Recess taken from 4:37 p.m. to 4:43 p.m.) THE VIDEOGRAPHER: With the	Page 309
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Page 310 Page 312 1 example, marketing of the laser-cut 1 about during this particular trial? 2 mesh, post-marketing, they didn't --2 A. No. As I sit here today, no. 3 3 MS. SUTHERLAND: All right. they didn't do appropriate testing 4 4 I'm going to hand it to co-counsel for either. 5 5 any questions and maybe save three If I were to be asked what type 6 of study should have been done, I will 6 minutes for my follow-up questions. 7 respond to that. I don't know if I'm 7 MS. VERBEEK: I'll reserve. 8 going to be asked that kind of guestion. 8 MS. SUTHERLAND: How much time 9 I could certainly opine about what types 9 do we have? 10 of testing should have been done, but 10 THE VIDEOGRAPHER: Nine 11 the testing was inadequate. 11 minutes. BY MS. SUTHERLAND: 12 12 MS. SUTHERLAND: All right. 13 Q. Okay. Let me ask it this way: Do 13 Let's go off. We'll switch. you intend to opine that Ethicon should have 14 14 THE VIDEOGRAPHER: With the done clinical testing of TVT-O before 15 15 approval of counsel, going off the marketing the TVT-O? record. The time is approximately 16 16 17 A. Yes. 17 4:47 p.m. 18 Q. All right. Are you intending to 18 (Recess taken from opine as to a specific number of women that 4:47 p.m. to 5:06 p.m.) 19 19 20 should have been enrolled in a clinical 20 THE VIDEOGRAPHER: With the trial pre-market? 21 approval of counsel, back on the record. 21 22 A. I don't intend to offer a specific 22 The time is approximately 5:06 p.m. 23 number of women because, as you and I have 23 discussed before, in order to arrive at a 24 **EXAMINATION** 24 specific number of women -- I could give 25 25 BY MR. GOSS: Page 311 Page 313 potentially a range that would have been 1 Q. Good almost evening, Dr. Pence. 1 2 appropriate, but in order to arrive at a 2 A. Good evening. 3 specific number, one has to design the 3 Q. For the record, we met before. I'm 4 Tim Goss. You know I represent Jennifer studv. 4 5 What the endpoints are. If it's a 5 Ramirez. 6 comparative study, what the differences one 6 A. Yes. 7 expects to see or no differences between 7 Q. And I retain -- my firm retained a -- one product and another depending on 8 8 you as an expert for her case. what type of trial it is. Then one then 9 A. Yes. needs to give that information to a 10 Q. And we are in Newport Beach, 10 statistician who does his calculations to California, and you are giving your 11 11 let you know how many patients you need to 12 deposition in that case today; is that 12 include considering the possibility for 13 13 right? dropouts in order to be able to end up with A. Yes, I am. 14 14 15 the right number of patients to be able to 15 Q. And you've given your deposition answer the questions you're intending to ask before? 16 16 by your protocol. 17 17 A. I have. 18 Q. One is the loneliest number. 18 Q. You understand that this case may A. One meaning a person. go to trial in San Antonio, Texas? 19 19 20 Q. So as you sit here today, have you, 20 A. Yes, I do. in fact, designed a protocol that you intend Q. And do you understand that your 21 21 to opine about with respect to TVT-O -testimony today is as if you are sitting in 22 22 that courtroom talking to that jury? 23 strike that. 23 24 As you sit here today, have you put 24 A. Yes, I do. together a protocol that you intend to opine 25 Q. Okay. And you've testified before 25

1 juries before? 2 A. Yes, I have. 3 Q. Okay. Where do you currently 4 reside? 5 A. Newport Beach, California. 6 Q. And where did you reside before 7 that? 8 A. Newberry Park, California. 9 Q. You just recently moved to Newport? 10 A. That's correct. 11 Q. Why did you move to Newport? 12 A. My son and his family, including my 13 three grandchildren, live in Newport Beach. 14 Q. Where did you grow up? 15 A. I grew up in the south in Texas. 16 Q. Where did you grow up? 17 A. I of New Braunfels and Wichita 18 Falls, Texas. 19 Q. So you're a little familiar with 20 San Antonio, Texas? 21 A. Yes, I am. 22 Q. Okay. Let me mark your CV. I'm 23 going to hand you what's been marked as 24 Pence Exhibit 14. 25 A. Thank you.  10 (Exhibit Number 14 was marked for identification.) 26 Q. Okay. Let me mark your personal CV? 27 A. Yes, it is. 28 Q. Okay. I'm going to walk through a little bit of this, and I'm not going to spend a lot of time on it, but I do want the jury to get a flavor of your education, your employment, and why you're an expert in this case. Okay?  10 Q. Okay. Ure not onleps?  11 Cexhibit Number 14 was marked for identification.) 3 By Ms. SUTHERLAND: 4 Q. Okay. L'm going to walk through a little bit of this, and I'm not going to spend a lot of time on it, but I do want the jury to get a flavor of your education, your employment, and why you're an expert in this case. Okay?  10 Q. Okay. Ure not olded evice and pharmaceutical product development. It plury dor on animals predicting what may happen in	2 3 4 5 6 7		1		
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Q. Okay. Where do you currently reside? A. Newport Beach, California. Q. And where did you reside before that? A. Newberry Park, California. Q. You just recently moved to Newport? A. That's correct. Why did you move to Newport? A. That's correct. Why did you move to Newport? A. My son and his family, including my three grandchildren, live in Newport Beach. Q. Where did you grow up? A. I grew up in the south in Texas. Q. Where in Texas? A. Yes, I am. Q. So you're a little familiar with San Antonio, Texas? A. Yes, I am. Q. Okay. Let me mark your CV. I'm Q. Okay. I'm going to walk through a It little bit of this, and I'm not going to Sepand a lot of time on it, but I do want the Jury to get a flavor of your education, your employment, and why you're an expert in this query the correct of science. Q. Okay. I'm going to walk through a pharmaceutical product development. It focuses on the study of the potential and help people to feel better, lobe better, better quality of life. Q. After you obtained your degree. It did you get in the science and help people to feel better, to be better, better quality of life. Q. And is that you get another degree? A. Yes, I did. A. Yes, I did.	3 4 5 6 7	juries before?	1	Q. And what type of degree was your	
4 reside?  A. Newport Beach, California. Q. And where did you reside before that?  A. Newberry Park, California. Q. You just recently moved to Newport? A. That's correct. Q. Why did you move to Newport? A. My son and his family, including my three grandchildren, live in Newport Beach. Q. Where did you grow up? A. I grew up in the south in Texas. Q. Where in Texas? A. I of New Braunfels and Wichita Falls, Texas. Q. So you're a little familiar with A. Yes, I am. Q. Okay. Let me mark your CV. I'm going to hand you what's been marked as Pence Exhibit 14. A. Thank you.  A. That's correct. Q. Where did you grow up? A. Yes, it is. Q. Okay. Let me mark your CV. I'm going to hand you what's been marked as Pence Exhibit 14. A. Thank you.  A. Yes, it is. Q. Okay. I'm going to walk through a little bit of this, and I'm not going to spend a lot of time on it, but I do want the jury to get a flavor of your education, your employment, and why you're an expert in this case. Okay? Where did you go to college?  4 Q. Okay. Why did you get it in searches? A. From the time I was a little girl, as far back as I can remember, I was always in the temelical field and in science and doing something to contribute and help people to feel better, to be better, better quality of life.  10 and help people to feel better, to be better, better quality of life.  12 Q. After you obtained you rdegree, your bachelor of science in microbiology, did you do further studies?  13 your bachelor of science in microbiology, did you do further studies?  14 A. Eventually I did, yes. Q. And did you get another degree? A. Yes, I did. Q. What did you get another degree? A. Yes, I did. Q. What did you get another degree? A. Yes, I did. Q. What did you get another degree? A. Yes, I did. Q. What did you get in the south of further studies?  A. Yes, I am. Q. What did you get another degree? A. Yes, I did. Q. What did you get another degree? A. Yes Q. Where was that? Q. Where was that? A. Yes. Q. You're not a medical doctor? A. No, I'm not. Q. Why don't you explain	4 5 6 7	A. Yes, I have.	2	major?	
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6 Q. And where did you reside before 7 that? 8 A. Newberry Park, California. 9 Q. You just recently moved to Newport? 10 A. That's correct. 11 Q. Why did you move to Newport? 12 A. My son and his family, including my three grandchildren, live in Newport Beach. 13 three grandchildren, live in Newport Beach. 14 Q. Where did you grow up? 15 A. I grew up in the south in Texas. 16 Q. Where in Texas? 17 A. I of New Braunfels and Wichita 18 Falls, Texas. 19 Q. So you're a little familiar with 20 San Antonio, Texas? 21 A. Yes, I am. 22 Q. Okay. Let me mark your CV. I'm going to hand you what's been marked as 24 Pence Exhibit 14. 25 A. Thank you.  Page 315 1 (Exhibit Number 14 was marked for identification.) 2 Page 315 2 Q. Okay. I'm going to walk through a little bit of this, and I'm not going to sand a lot of time on it, but I do want the jury to get a flavor of your education, your employment, and why you're an expert in this case. Okay? Where did you go to college?  6 A. From the time I was a little girl, as far back as I can remembeer, I was a lister predical field and in sinterested in the medical field and in science and doing something to contribute and help people to feel better, be thetr quality of life.  2 Q. After you obtained your degree, the tetter, be better, pother and help people to feel better, better quality of life.  2 Q. After you obtained your degree, the tetter, better quality of life.  2 Q. After you obtained your degree, the tetter, better quality of life.  2 Q. And did you get another degree?  4 A. Yes, I did.  8 Q. What did you get another degree?  4 A. A got a doctor of philosophy or a Ph.D. degree with a major in toxicology, a minor in pharmacology.  9 Q. Where was that?  2 Q.	6 7	reside?	4	Q. Okay. Why did you get it in	
7 that? 8 A. Newberry Park, California. 9 Q. You just recently moved to Newport? 10 A. That's correct. 11 Q. Why did you move to Newport? 12 A. My son and his family, including my 13 three grandchildren, live in Newport Beach. 14 Q. Where did you grow up? 15 A. I grew up in the south in Texas. 16 Q. Where in Texas? 17 A. I of New Braunfels and Wichita 18 Falls, Texas. 19 Q. So you're a little familiar with 19 San Antonio, Texas? 20 Q. So, you're a little familiar with 21 Q. Where exist on the madical flow of part of science in microbiology, did you do further studies? 17 A. Yes, I did. 18 Falls, Texas. 19 Q. So you're a little familiar with 20 San Antonio, Texas? 21 A. Yes, I am. 22 Q. Okay. Let me mark your CV. I'm 23 going to hand you what's been marked as 24 Pence Exhibit 14. 25 A. Thank you.  Page 315 1 (Exhibit Number 14 was marked for identification.) 2 Q. Okay. Lim going to walk through a fittle bit of this, and I'm not going to spend a lot of time on it, but I do want the jury to get a flavor of your education, your employment, and why you're an expert in this case. Okay?  Where did you go to college?  7 as far back as I can remember, I was interested in the medical field and in on the medical fled and in the by contribute and help people to feel better, to be better, better quality of life.  Q. After you obtained your degree, 2d. After you obtained your degree. 2d. A. Yes, I did, Vull A you do do further studies?  A. Yes, I did, Ves. 2d. A yes, I did, Ves. 2d. A yes and doctor of philosophy or a Ph.D. degree with a major in toxicology, a minor in pharmacology. 2d. Ph.D. degree with a major in toxicology a minor in pharmacology. 2d. Ph.D. degree with a major in toxicology and interested in the medical fled and in toxicol	7	A. Newport Beach, California.	5	science?	
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113 A. 1 dia my undergraduate work at   13 humans.	8 9 10 11		13	humans.	
, ,	8 9 10 11 12	, 5		O. And you got your Ph.D. in	
, , , , , , , , , , , , , , , , , , , ,	8 9 10 11 12 13				
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17 A. No. I was actually born in 17 Q. Tell the jury a little bit about	8 9 10 11 12 13			•	
,	8 9 10 11 12 13 14 15 16	•		· ,	
19 Q. Okay. Did you get a degree at 19 A. It requires, of course, a lot of	8 9 10 11 12 13 14 15 16 17	•		- · · ·	
	8 9 10 11 12 13 14 15 16 17				
,	8 9 10 11 12 13 14 15 16 17 18 19		20	didactic training, a large amount of	
	8 9 10 11 12 13 14 15 16 17 18 19 20	•		didactic training, a large amount of coursework, and then for a Ph.D., it	
1	8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes, I did.	21	coursework, and then for a Ph.D., it	1
, , , , , , , , , , , , , , , , , , , ,	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes, I did. Q. And what did you get that degree	21 22	coursework, and then for a Ph.D., it requires independent research and presenting	J
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	8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	<ul><li>A. Yes, I did.</li><li>Q. And what did you get that degree in?</li><li>A. My major was microbiology with</li></ul>	21 22 23	coursework, and then for a Ph.D., it requires independent research and presenting	J

Page 318 Page 320 being examined on those results by your 1 Lilly and Company. 2 committee, and they're assuring that you 2 Q. Is Eli Lilly and Company similar to meet the qualifications to receive your 3 3 Johnson & Johnson and Ethicon? 4 4 receive your Ph.D. degree. MS. SUTHERLAND: Objection. 5 THE WITNESS: Yes. It's a 5 Q. You got a minor in pharmacology. 6 Explain to us what pharmacology is. 6 large pharmaceutical company. 7 A. Pharmacology -- toxicology is a 7 BY MR. GOSS: 8 subset of pharmacology. Pharmacology is the 8 O. Okay. And what did you do for Eli study of both the adverse effects as well as 9 9 Lilly? 10 the -- more principally the effects of drugs 10 A. I started out working in a basic 11 that are positive, how -- the beneficial 11 research laboratory developing various types effects of drugs, how they act on the body, of assays and doing animal research in 12 12 how the body responds to them. the -- in immunology. 13 13 O. So the study of toxicology and O. What year was that? 14 14 pharmacology would include the study of the A. 1970. 15 15 benefits and risks of drugs? Q. 1970? 16 16 A. That's correct. A. 1970. 17 17 Q. So for almost 40 years, have you 18 Q. Okay. How long does it generally 18 been either working with the industry or for take for someone to get a Ph.D. in 19 19 20 20 a pharmaceutical company? toxicology? A. It generally takes four to five 21 A. This is my 47th year of work, I 21 years after -- once one enters the program. think, when I calculated it recently. 22 22 Q. And has that all been encompassed 23 In my case, it took, if I recall correctly, 23 a little over seven years because I was also 24 with either being employed by pharmaceutical 24 working full-time for a large part of that companies or advising pharmaceutical 25 25 Page 319 Page 321 time and raising a couple of children. 1 companies or manufacturers? 1 2 Q. Right. Are you currently employed? 2 A. Yes. And one part of that period, 3 A. Yes, I am. 3 there was a three-year period where I was Q. And how are you currently employed? still employed by Eli Lilly and Company but 4 5 A. I am employed by Symbion Research 5 worked in developing cosmetics. There are International. 6 correlations between -- cosmetics are also 6 7 Q. Okay. What is Symbion? 7 regulated by the FDA. 8 8 A. Symbion is a consulting company and Q. I saw you also worked for Serono. contract research organization. We work 9 Is that how you say it? with companies like medical device 10 A. Yes, it is. 10 companies, pharmaceutical companies, Q. What kind of company is that? 11 11 companies developing biological therapeutics 12 12 A. Serono Laboratories is also a to assist them with understanding what the 13 13 pharmaceutical company. requirements are, what they need to do to 14 14 Q. You worked for Triton? 15 bring their products to the market, assuming 15 A. Yes, I did. that the products turn out to be safe and Q. What is Triton? 16 16 effective through all the appropriate A. Triton was a pharmaceutical 17 17 18 testing, and we work with them to help get 18 company, a biotechnology company. It was, their products through the FDA process prior at the time, a wholly owned subsidiary of 19 19 to marketing and post-marketing. 20 Shell Oil Company, and ultimately Shell --20 it was acquired by Berlex. 21 Q. That's how you're currently 21 22 employed. Now I'm going to back you way up. 22 Q. And you worked for Amgen? When you got out of school, where A. Yes, I did. 23 23 24 did you go to work? 24 Q. What's Amgen? 25 A. My first job after school was Eli 25 A. Amgen is probably the major

Page 322 Page 324 1 independent biotechnology company in the 1 the TVT-O; is that right? 2 2 MS. SUTHERLAND: Objection. country. 3 3 Q. After Amgen, then you went to work THE WITNESS: That is correct. 4 with Symbion? 4 BY MR. GOSS: 5 A. Yes. For a three-year period prior 5 Q. Did you have any experience in to incorporating at Symbion, I operated as 6 product development in your early 6 7 an independent consultant and then 7 employment? 8 incorporated Symbion Research International, 8 A. Yes. My whole career has been founded the company in 1995. 9 9 involved in one aspect or another of product 10 Q. Okay. I'm going to ask you just an 10 development. In particular at Triton, I was overview of some things that you did for 11 11 a project manager where I was responsible these companies while you were working for for oversight of product development from 12 12 basic research all the way through in 13 them. 13 preparation for market launch. 14 Did you design clinical trials? 14 A. I did. Many. 15 15 BY MR. GOSS: Q. What's a clinical trial? Q. At any of these companies, did you 16 16 A. A clinical trial is a research hold responsibility for making sure the 17 17 18 study in humans, and a clinical trial 18 companies were complying with industry specifically is one where patients are 19 standards? 19 20 randomly -- are assigned prospectively, I 20 MS. SUTHERLAND: Objection. should say, to one or more treatments. 21 THE WITNESS: Always, yes. 21 Q. Did you do laboratory work? 22 22 Especially once we got into the regulatory and clinical development 23 A. Yes. 23 24 Q. Did you deal with clinical affairs? 24 area, and that was particularly in 1997. A. Yes. 25 25 I'm sorry. 1977. Page 323 Page 325 Q. What's clinical affairs? 1 BY MR. GOSS: 1 2 A. Clinical affairs is the group 2 O. What was that in connection with? 3 within companies that deals with the human 3 A. I transferred at Eli Lilly and phase of testing of products. 4 4 Company into the clinical and regulatory 5 5 Q. Did you -- were you responsible for area. 6 collecting data? 6 Q. And so you were in the clinical and 7 A. Yes, I was. Many times. 7 regulatory area at Eli Lilly? 8 Q. Okay. What types of data? 8 A. Yes. As a medical information --9 A. A variety of types of data. All 9 and my title was medical information the types of data that are collected in 10 administrator. 10 clinical -- in a clinical trial or any type Q. What did that entail? 11 11 A. A variety of -- a variety of roles, 12 of clinical study where one is looking -- is 12 administering one or more types of treatment if you will. I was responsible for working 13 13 to a patient, different patients, human pre-marketing and with data pre-marketing 14 14 15 subjects, and evaluating the outcome, both 15 and post-marketing. In some aspects, I safety and effectiveness data. actually monitored clinical trials, meaning 16 16 So it would include data to that I would go out to the investigative 17 17 18 determine whether or not the product is 18 sites where the studies were being conducted working for its intended use. It would to make sure that the physicians and the 19 19 include adverse reaction information and physician staff were conducting the study 20 20 clinical laboratory information, a whole according to the protocol, which is the 21 21 document that describes how a study should 22 scope of information including patient 22 demographics. be conducted and according to regulations as 23 23 Q. Part of what you've done in this 24 24 well. 25 case is look at the product development for 25 And I was responsible for

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collect -- to evaluating data and tabulating data, both pre-marketing and post-marketing, in particular adverse event data.

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For example, I worked on the very first recombinant DNA product ever to be marketed, which was human insulin, and one of my roles at Eli Lilly was involvement in the collection of data once the product went on the market, safety data in particular, to present to FDA.

There are certain requirements, regularly reporting of adverse event data post-marketing of a new drug such as that.

- Q. What experience have you obtained over your 40-something years in the industry with respect to labeling of product, drugs, and devices?
- A. Again, a variety of experience. In terms of clinical trials, there's a document called the Investigator's Brochure. It's also been termed proto labeling. It's 21 22 basically for products prior to their marketing, it is the document that provides the same type of information that's included

in a package insert for a drug or in the

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- 1 trials, through reports of complaints,
- 2 adverse events that are reported to the
- 3 company once the product is on the market as

Page 328

Page 329

- 4 well as in reviewing the medical and
- 5 scientific literature for reports of adverse 6 events.

7 So I've done that post-marketing, 8 and on the pre-marketing side in terms of

- 9 clinical trials, as I may have mentioned
- 10 earlier, constantly evaluating adverse
- 11 events that are being -- that are occurring
- 12 during clinical trials, assessing those,
- 13 very serious ones that are unexpected that
- meet certain criteria, reporting those to 14
- the FDA in a required time frame and 15 submitting them to doctors as well. 16
  - O. Have you consulted with companies with respect to regulatory matters?
    - A. Yes, frequently.
- 20 Q. Is that mostly with Symbion?
  - A. It's not only with Symbion. Prior
- 22 to that, while my roles were in clinical and
- 23 project management, within companies such as
- 24 Eli Lilly, Amgen, work is done -- all the
- 25 companies where I've worked, work is done as

context of a medical device and instructions for use or directions for use, which we refer to as an IFU or a DFU.

The purpose of that is to give the physician the information that he or she needs to be able to use the product safely and effectively based on the known information.

So I've prepared a number of those Investigator's Brochures over my career, written them in their entirety, and then I've also been involved in the review and/or development of IFUs, for example, for medical devices.

- 15 Q. Have you been involved in safety surveillance? 16
- A. Yes. 17
  - Q. What is safety surveillance?
- A. Safety surveillance -- are you 19
- talking about post-marketing safety 20 21 surveillance in particular?
- 22 O. Sure.
- A. It is evaluating the safety data 23
- 24 that is available once a product goes on the 25
  - market through post-marketing clinical

Page 327 1 a part of a project team, and I've been

- 2 involved in preparing many submissions to
- 3
- the FDA, presenting -- prior to being at Symbion, starting at Symbion, I've presented 4
- 5 to FDA on many occasions the proposed plan
- for the studies that we were going to 6
- 7 conduct.

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I've been involved in an advisory committee meeting as well preparing the information for that post-marketing.

- Q. How many pharmaceutical and/or device companies have you advised over your 40-plus years in the industry?
- A. Over 80.
- Q. Involving how many drugs or
- devices? 16
- 17 A. Over 90.
- 18 Q. Do you have experience with
- Class 1, Class 2, and Class 3 medical 19
- 20 devices?
  - A. Yes, I do.
- 22 Q. How did you obtain that experience?
- A. The majority of that experience was 23
- obtained after I started my own consulting 24
- 25 practice beginning in 1992 and then through

Page 330 Page 332 Compassion -- of CompassioNow. 1 Symbion as well. 1 2 Q. Have you advised manufacturers with 2 Q. What is that? 3 3 respect to the adequacy of their medical A. CompassioNow is a nonprofit 4 device labeling? 4 organization. We have our 10th anniversary 5 5 this year. It was started with the vision A. Yes, I have. 6 Q. Have you advised manufacturers with 6 of providing medical care to the world's 7 respect to whether or not they should 7 least served. We've been working in 8 perform clinical studies? 8 Sub-Saharan Africa, South Africa, Tazania, Zambia, for example, to provide support for 9 A. Yes, I have. 9 nurses and doctors and help to educate local 10 Q. And what types of studies to 10 11 perform? 11 people so that they can help to run 12 A. Absolutely. I've designed the 12 community clinics, providing medical supplies, both drugs and various equipment. 13 clinical studies on many occasions. 13 There are people in these areas 14 O. Did you, during this time period, 14 gain expertise in the review and analyzing that have -- they don't even have Band-Aids. 15 15 of medical literature? Q. I can tell you're proud of that 16 16 17 A. Yes. 17 work. 18 MS. SUTHERLAND: Objection. 18 A. I am. It's important. We have 19 BY MR. GOSS: 19 served a lot of people, and it's made a 20 Q. When I use the term "medical 20 difference. literature," why don't you tell the jury 21 Q. Do you now or have you served on 21 22 what that means. 22 the clinical trials certificate program 23 A. Talking about publications that are 23 advisory board? 24 in typically peer-reviewed journals where 24 A. Yes. I did in the past. scientists, clinicians publish results of 25 25 Q. What is that? Page 331 Page 333 their research, both pre-clinical research, 1 A. The intent of that advisory 1 2 meaning testing that's not in humans, maybe 2 board -- it was run through the California laboratory research in in vitro, which is 3 State University system -- was to develop a 3 certification program for people that were 4 test tube, Petri-dish-type testing, benchtop 4 5 testing, as well as testing in animals and 5 both students, usually graduate level 6 also testing in humans. 6 students, or people already working in a related field that were interested in 7 7 For a peer review, a draft 8 8 publication is submitted to a journal, and a furthering their career and getting into group of peers, if you will, who are 9 clinical development. experienced in the field that is covered by 10 And it was intended to be a 10 the specific publication, review the certification program to train them about 11 11 12 publication, typically will critique it and 12 how to do clinical trials. 13 often will request revisions and decide 13 O. You spoke a little bit about RAPS, whether or not that the publication -- that which as I understand it, Regulatory Affairs 14 14 15 the data in the publication in the paper is 15 Professional Society. worthy of publication. 16 16 A. Yes. Q. Okay. Let's shift gears a little Q. And you were a RAPS fellow; is that 17 17 18 bit. I want you to -- I want to talk a 18 right? little bit about your boards and 19 19 A. Yes. memberships. 20 O. What is a RAPS fellow? 20 21 Are there certain boards that you 21 A. I'm very honored to be a RAPS 22 belong to? 22 fellow. Pardon me. A RAPS fellow is a A. Yes, either now or in the past. peer-reviewed credential. RAPS fellows were 23 23 first designated in 2008. A committee of 24 Q. Right. What are those? 24 25 A. I'm currently on the board of the 25 peers who are senior level professionals who

Page 334 Page 336 Q. What's the regulatory training have met the highest level of regulatory 1 achievement review one's credentials, and 2 2 course faculty? A. That, if I understand your one must have a minimum of 15 years of 3 3 4 regulatory experience and then based on 4 question, that, through the Drug Information 5 5 one's management and leadership experience Association, in the past, I have taught in and their contributions to the field of 6 6 that program. 7 regulatory affairs, the committee, which 7 Q. What is -- I see that you're RAC 8 I've actually served on also for several 8 certified. What is that? years since becoming a RAPS fellow, makes a 9 A. That's regulatory affairs determination as to whether or not one certification. That is a certification that 10 10 11 qualifies to be a RAPS fellow. 11 is offered through the Regulatory Affairs Professional Society. It is the -- again, 12 There are, at this point in time as 12 of December 2015, 98. is a credential that -- this one in 13 13 Q. When did you become a RAPS fellow? 14 14 particular is not a peer-reviewed A. 2009. 15 15 credential. Q. How many were there in 2009, It's achieved by taking a test 16 16 that's been designed to test one's level of 17 roughly? 17 18 A. 20 to 30 or fewer than 20. I don't 18 regulatory expertise, and through the recall the specific number. testing, if you pass the test, you can 19 19 20 Q. And that's a Regulatory Affairs 20 become regulatory affairs certified. And **Professional Society?** 21 once you become regulatory affairs 21 A. A fellow, yes. 22 certified, every three years you're required 22 Q. And that's for people that have a to submit continuing education and 23 23 24 particular expertise and have been 24 leadership information to show that you're recognized for their abilities in regulatory active and still working in the top of your 25 25 Page 335 Page 337 affairs? 1 field, if you will. 1 2 2 O. Do you consider yourself a MS. SUTHERLAND: Objection. regulatory affairs expert? 3 Leading. 3 THE WITNESS: That's correct. A. Yes, I do. 4 4 5 That's correct. One must have achieved 5 Q. Okay. In addition to all that, you 6 the highest level of achievement. 6 also work on cases like this? 7 7 BY MR. GOSS: A. Yes. 8 8 Q. Let's talk a little bit about your Q. Okay. Do you accept every case that's presented to you? 9 teaching experience. 9 First of all, do you have any 10 A. No, I don't. 10 Q. Do you charge for your time just teaching experience? 11 11 like anybody else would? 12 A. I do. 12 13 Q. And what is your teaching 13 A. I do. Q. Charge for your time just like when 14 experience? 14 15 A. I've taught clinical trials and 15 you consult with a manufacturer? project management in the clinical trial 16 16 A. Correct. certificate program that we talked about a 17 17 Q. Have you testified before in a mesh 18 short while ago. I've also -- I also was 18 case? asked to develop and teach. So I'm 19 19 A. Yes, I have. part-time faculty at the California State 20 Q. Have you been accepted by courts in 20 University on the Channel Islands campus Texas as an expert in a mesh case? 21 21 teaching master's students who are getting MS. SUTHERLAND: Objection. 22 22 their master's degree in biotechnology, a THE WITNESS: Yes, I have. 23 23 course entitled "Clinical Trials and Quality 24 24 BY MR. GOSS: 25 Assurance." 25 Q. Okay. Let's move on to another

Page 338 Page 340 BY MR. GOSS: area. I want to talk with you -- I kind of 1 2 want to get some definitions down so that 2 Q. What's stress urinary incontinence? the jury kind of understands where we're 3 3 A. Stress urinary incontinence, you'll 4 going with some things. 4 probably hear me refer to it for short as 5 5 What is J&J? J&J is a term that SUI, is involuntary leakage of urine with 6 the jury is going to hear. What is J&J? 6 coughing, for example, jumping, types of 7 A. Johnson & Johnson. 7 exercise that cause intraabdominal pressure. 8 O. Okay. What does Johnson & Johnson 8 O. Is stress urinary incontinence a 9 do? 9 life-threatening condition? 10 A. Johnson & Johnson is a company that 10 A. No, it is not. 11 develops a variety of products. Amongst 11 Q. We're going to talk today about the TVT obturator system. What's the TVT those products are medical devices as well 12 12 as pharmaceutical products through various 13 13 obturator system? divisions of Johnson & Johnson. 14 14 A. It's the tension-free vaginal mesh that is a sling for the treatment of SUI, 15 Q. What is Ethicon? 15 A. Ethicon is a division of Johnson & and it -- tension-free vaginal tape, 16 16 Johnson. In this case that we're talking sometimes the T is -- sometimes is referred 17 17 18 about today, it is the division or the part 18 to as a tape instead of a sling. of Johnson & Johnson, if you will, that And this particular, the obturator 19 19 20 manufactures and markets the pelvic mesh 20 means that it is -- that refers to the 21 insertion technique. 21 products. 22 MS. SUTHERLAND: I'm going to 22 Q. Okay. Let's back up a little bit on that. The jury is going to hear about 23 object to foundation just on the 23 24 response on J&J as to what they do. 24 the TVT retropubic --A. Yes. 25 BY MR. GOSS: 25 Page 339 Page 341 Q. What is the FDA? 1 Q. -- and the TVT obturator. 1 2 A. The United States Food and Drug 2 A. Yes. 3 Administration. It is the agency within the 3 O. Also known as the TVT-O. federal government that is responsible for 4 4 A. Yes. 5 oversight of the public health in particular 5 Q. What's the difference? 6 with regard to a number of different A. Okay. The tension-free vaginal 6 7 products. A large number of products that 7 tape, TVT retropubic, it's the insertion we all deal with on a daily basis, including 8 method. And the insertion method is 8 not only medical devices and drugs, but 9 through -- well, it can be inserted two certain types of foods, cosmetics, tobacco, 10 10 ways. veterinary products. The insertion begins in the vagina, 11 11 O. The jury's heard about transvaginal 12 12 in the female vagina, and then it exits in synthetic mesh slings. the lower abdomen. It can also be inserted 13 13 suprapubicly so that the insertion begins in 14 A. Yes. 14 15 Q. Or mesh slings or slings. 15 the abdomen and then comes through the What is that? vagina. So it fits under the urethra, if 16 16 A. The transvaginal mesh sling, what you will, and the urethra is the tube that 17 17 leads from the bladder to the exit through 18 we're talking about here today, those slings 18 are made of a plastic, which is 19 19 which one urinates. polypropylene, for the treatment of stress 20 O. What's the TVT-O obturator or the 20 21 urinary incontinence. 21 TVT-O? 22 Q. When we talk about polypropylene, 22 A. The insertion route is -- it's an we're talking about plastic. inside-out technique. It starts in the 23 23 24 A. Yes. 24 vagina, and instead of going up and the 25 25 exiting through the abdomen, lower abdomen, MS. SUTHERLAND: Objection.

Page 342 Page 344 1 it exits in the thigh or the groin area 1 of that code, is that human subjects must 2 going through the obturator -- the obturator 2 be -- must be informed about any treatment membrane and the obturator muscle area. 3 3 or any procedure that is going to be done to 4 4 them and consent. Certainly, that's true in O. Which product was developed first 5 5 the context of research. It's also true in by Ethicon? 6 A. The TVT. The retropubic. 6 the context of practice. 7 Q. And then did Ethicon develop the 7 In fact, there's a position 8 8 statement from the American College of TVT-O? 9 A. Yes. 9 Obstetrics and Gynecologists that talks Q. What's the IFU? about the concept of respect for persons 10 10 11 A. The IFU is short for instructions 11 which is essentially what informed consent does. It's respect for persons in that the 12 for use. It is what we call professional 12 individual is informed of all the potential 13 labeling. It is the cornerstone of risk 13 management because it is the document, the risks and benefits so that they have a right 14 14 primary communication between the to self-determination for their medical 15 15 manufacturer of the product, in this case, 16 16 care. the TVT-O sling, and the surgeon who's going 17 17 MS. SUTHERLAND: Objection. 18 to be using that product. 18 Nonresponsive. And it is intended to provide all 19 19 BY MR. GOSS: 20 of the necessary information to enable the 20 Q. What role does the IFU play in the physician to use that product safely and 21 concept of informed consent? 21 effectively, to consult and advise the 22 22 A. The IFU is the document that patient with regard to the risk, potential 23 23 provides the information about the product 24 risk as well as the potential benefit of the 24 including risks, potential risks, as well as product so that together the patient and potential benefits, to the surgeon or the --25 25 Page 343 Page 345 the -- the physician and the patient can 1 in this case, and that information in 1 2 2 make a determination as to whether or not consenting a patient as to whether or not, 3 this is the right product to be used for the 3 in this case the TVT-O, would be used on a patient's treatment of SUI or should an 4 4 particular patient. 5 5 alternative procedure or treatment be used. That document provides the 6 Q. What does IFU stand for? 6 information for the doctor to share that 7 7 with the patient, what the risks may be and A. Instructions for use. 8 8 whether or not the patient makes a decision, Q. Okay. And does that come packaged 9 with the product? 9 self-determination, as to whether or not 10 A. Yes, it does. 10 this is a procedure considering the risks 11 Q. We'll be talking a little about the that she wants to undertake. 11 concept of informed consent. 12 12 It also is intended to provide the 13 What is informed consent? 13 information that enables the physician, as I 14 A. Informed consent has -- its -mentioned earlier, to make a decision as to 14 whether or not -- because there are 15 current day, informed consent really has its 15 origins in the Nuremberg Code following the alternative treatments available -- whether 16 16 second world war. The Nuremberg Code was 17 17 or not this is the right treatment for a 18 developed as a means of evaluating the 18 particular patient. scientists and physicians who had Q. If the IFU is inadequate, what 19 19 20 participated in experimentation on patients 20 effect does that have on informed consent? in the -- in Germany during the second world 21 21 MS. SUTHERLAND: Objection. 22 war, and that was the code that was then the 22 Speculative. beginning of other codes which have been 23 23 THE WITNESS: If it is 24 developed. 24 inadequate, then full -- particularly 25 And the key, the very first point 25 with regard to complications and risks,

			1		1
	•	Page 346			Page 348
1	then the patient cannot be truly	3	1	Q. Okay. In the hundreds of	
2	cannot provide true informed consent		2	thousands?	
3	because information about risks is		3	MS. SUTHERLAND: Objection.	
4	missing.		4	Leading.	
5	BY MR. GOSS:		5	THE WITNESS: Very well may be.	
6			6	BY MR. GOSS:	
	Q. Does that have an effect on public		7		
7	safety?			Q. Okay. Did you review testimony of	
8	MS. SUTHERLAND: Objection.		8	Ethicon witnesses?	
9	THE WITNESS: Yes, it does.		9	A. Yes.	
10			10	Q. Did you review trial testimony?	
11	BY MR. GOSS:		11	A. Yes, I did.	
12	Q. Okay. Let me move on to another		12	Q. Did you review deposition	
13	topic.		13	testimony?	
14	When you were retained in this		14	A. Yes.	
15	case, did you conduct an investigation into		15	Q. Testimony like you're giving today?	
16	Ethicon's practices?		16	A. That's correct.	
17	A. Yes, I did.		17	Q. What areas of Ethicon were these	
18	Q. And what did you do to conduct that		18	employees that were giving their deposition,	
19	investigation?		19	what areas were they in?	
20	A. I reviewed a large volume of		20	A. A variety of areas. I mentioned	
21	materials, which included deposition		21	earlier that companies like Ethicon have a	
22	testimony of a large number of Ethicon		22	product project team, and there are	
23	employees. I also evaluated documentation		23	different groups that have different	
24	that's been produced in this litigation. I		24	expertises that contribute to the	
25	reviewed scientific and medical literature.			•	
25	reviewed scientific and medical illerature.		25	development of a project.	
		D 247			D 240
	I also evaluated thewhat's called the	Page 347	1	Co I have the various expertions	Page 349
1	I also evaluated the what's called the	Page 347	1	So I have the various expertises	Page 349
2	MAUDE, a manufacturing user facility device	Page 347	2	that would contribute to the development of	Page 349
2 3	MAUDE, a manufacturing user facility device experience database, which is a publicly	Page 347	2	that would contribute to the development of a project, I've reviewed depositions from	Page 349
2 3 4	MAUDE, a manufacturing user facility device experience database, which is a publicly available database of what are called	Page 347	2 3 4	that would contribute to the development of a project, I've reviewed depositions from people in those different areas which	Page 349
2 3 4 5	MAUDE, a manufacturing user facility device experience database, which is a publicly available database of what are called medical device reports, serious adverse	Page 347	2 3 4 5	that would contribute to the development of a project, I've reviewed depositions from people in those different areas which include clinical and medical affairs,	Page 349
2 3 4 5 6	MAUDE, a manufacturing user facility device experience database, which is a publicly available database of what are called medical device reports, serious adverse events, and malfunctions that could result	Page 347	2 3 4 5 6	that would contribute to the development of a project, I've reviewed depositions from people in those different areas which include clinical and medical affairs, pre-clinical, engineers, regulatory as well,	Page 349
2 3 4 5 6 7	MAUDE, a manufacturing user facility device experience database, which is a publicly available database of what are called medical device reports, serious adverse events, and malfunctions that could result in serious adverse events that FDA	Page 347	2 3 4 5 6 7	that would contribute to the development of a project, I've reviewed depositions from people in those different areas which include clinical and medical affairs, pre-clinical, engineers, regulatory as well, senior executives. It would also include	Page 349
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Page 350 Page 352 1 of the witnesses whose trial testimony and 1 industry standards with respect to the 2 deposition you have reviewed? 2 development and marketing of the TVT-O? 3 3 A. Yes, it is. A. Yes. 4 O. Does that refresh some of your 4 MS. SUTHERLAND: Objection. 5 5 recollection as to what areas some of them BY MR. GOSS: 6 6 are in? Q. And did you endeavor to do that 7 A. Yes. There are people in 7 review? 8 8 pre-clinical research, as I mentioned, as A. Yes, I did. 9 well as quality and medical affairs and 9 Q. How many hours do you think that 10 regulatory affairs and marketing. I think I 10 you spent conducting your investigation? had not mentioned marketing before. Medical 11 11 A. Hundreds of hours if you include not just specific for Ms. Ramirez's case but 12 directors. I've also reviewed professional 12 overall for the development of TVT and 13 education. 13 14 Q. Let me ask you this --14 TVT-O. Hundreds of hours. A. Oh. People reporting adverse 15 15 Q. In your review of that information events and reviewing adverse events. and the information that we've talked about 16 16 O. Did you also review medical so far, did you apply the same methodology 17 17 18 literature? 18 in the review of that information that you applied in your everyday work in consulting 19 A. Yes. 19 20 20 with other manufacturers and advising them? Q. Okay. What types of medical literature were available to you? 21 A. Yes. In this case, I actually had 21 22 A. The scope of medical literature 22 more information in the context of 23 that's available publicly. 23 deposition testimony. When I'm working with 24 Q. Okay. And did you review 24 companies, I interview the people that I'm peer-reviewed medical literature? 25 25 working with, but in this context, I had Page 351 Page 353 A. Yes. 1 enough numerous depositions that I could 1 2 2 O. And explain to the jury what review that also provided insight to what 3 peer-reviewed medical literature is. 3 happened. 4 A. Peer-reviewed is the process that 4 Q. You've talked a little bit about 5 means that a publication prior to being 5 some standards in the industry. You spoke 6 accepted for publication is -- someone 6 this morning about the GHTF principles. 7 wishing to publish a paper submits it to an 7 What's GHTF? appropriate journal that publishes the type 8 8 A. Global Harmonization Task Force. of data that the research that's in that --9 O. We'll talk a little bit about that that's in a particular paper addresses, and 10 later. 10 the journal has people who are experienced You spoke about the Blue Book? 11 11 in that field who review the paper and look 12 12 A. Yes. at it and critique it and provide feedback 13 13 O. What is that? to the authors of the publication. A. If I understand your question, the 14 14 15 And many times they'll ask 15 specific Blue Book memorandum that you're questions and have revisions made to the talking about is a particular FDA guidance 16 16 document that -- for medical device labeling paper prior to its publication, or sometimes 17 17 that sets the standards for medical device 18 if they don't feel that the information in 18 the proposed publication meets the 19 19 labeling. qualifications of the journal or deserves to 20 Q. In your review and in forming your 20 opinions, did you apply some of those be published, they'll deny publication. 21 21 Q. Did I retain you -- did my firm standards to the things that your 22 22 retain you on behalf of Ms. Ramirez to look investigation uncovered? 23 23 24 at the conduct of Ethicon and determine 24 A. Absolutely. 25 whether or not that conduct complied with 25 Q. Okay. Let me shift gears a little

		1		
	Page 354			Page 356
1	bit more. I want to talk to you about	1	must choose the safest product."	
2	safety principles. I'm going to hand you	2	Is that a principle that is	
3	some slides. I'm going to hand you what I	3	supported by the Global Harmonization Task	
4	have marked as Exhibit 16.	4	Force standards?	
5	(Exhibit Number 16 was	5	MS. SUTHERLAND: Objection.	
6	marked for identification.)	6	THE WITNESS: All other things	
7	BY MR. GOSS:	7	considered equal, yes.	
8	Q. Are these some slides that you	8	BY MR. GOSS:	
9	assisted me in preparing?	9	Q. And the fourth safety principle.	
10	A. Yes.	10	"Safety of patients has to be the number one	
11	Q. And do you recognize those slides?	11	priority, not corporate profits."	
12	A. Yes, I do.	12	Is that a safety principle	
13	Q. Okay. Let's talk about the first	13	supported by the Global Harmonization Task	
14	safety principle. When we say "safety	14	Force?	
15	principle," what do we mean?	15	MS. SUTHERLAND: Objection.	
16	MS. SUTHERLAND: Objection.	16	THE WITNESS: Yes. Patient	
17	THE WITNESS: That a product is	17	safety is always number one.	
18	safe for use, that there's a favorable	18	BY MR. GOSS:	
19	benefit-to-risk ratio.	19	Q. Is that a principle that is also	
20	BY MR. GOSS:	20	one that is supported by the credo of J&J	
21	Q. Well, is a safety principle	21	and Ethicon?	
22	something that a manufacturer should seek to	22	A. Yes, that is correct.	
23	comply with?	23	Q. When you investigated Ethicon	
24	MS. SUTHERLAND: Objection.	24	when you investigated Ethicon, did you find	
25	THE WITNESS: Absolutely.	25	a document that was a Johnson & Johnson	
	,.			
	Page 355			Page 357
1	Page 355 BY MR. GOSS:	1	credo?	Page 357
1 2	BY MR. GOSS:	1 2	credo? A. Yes, I did.	Page 357
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	BY MR. GOSS: Q. Let's talk about the first safety principle. "A corporation is required to make sure its products are reasonably safe." Is that a standard in the industry? A. Yes, it is. Q. Okay. And is that a standard in the industry that is set forth in the Global Harmonization Task Force documents? A. Yes, it is. Q. Okay. The second safety principle, "A corporation must investigate warning signs that its products may be dangerous and make sure that any problems with the product are fixed in a safe manner." Is that a safety principle that also has support in the Global Harmonization Task Force documents? A. Yes, that's correct. MS. SUTHERLAND: Objection. BY MR. GOSS: Q. Let's talk about the third safety principle. "If a corporation has two	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Yes, I did. This was attached to the back of these. Was it intended to be? Q. I'm handing you what's been marked as Exhibit 17. (Exhibit Number 17 was marked for identification.) BY MR. GOSS: Q. And what is this document? A. This is the Johnson & Johnson credo. Q. And are you familiar with this document? A. Yes, I am. Q. Let's talk a little bit about it. First of all, do you support this credo? A. Yes, I do. Q. Think it's a good idea? A. It is a good credo. Q. It says, at the beginning, "We believe our first responsibility is to the doctors, nurses, and patients, to mothers	Page 357
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1 Is that consistent with the safety 2 principles we just discussed? 3 MS. SUTHERLAND: Objection. 4 THE WITNESS: Yes, it is. 5 BY MR. GOSS:  Page 358 1 standard of care? 2 A. Yes. 3 MS. SUTHERLAND: 4 BY MR. GOSS: 5 Q. In your investigates.	Page 360
2 principles we just discussed? 2 A. Yes. 3 MS. SUTHERLAND: Objection. 3 MS. SUTHERLA 4 THE WITNESS: Yes, it is. 4 BY MR. GOSS:	
3 MS. SUTHERLAND: Objection. 3 MS. SUTHERLA 4 THE WITNESS: Yes, it is. 4 BY MR. GOSS:	
3 MS. SUTHERLAND: Objection. 3 MS. SUTHERLA 4 THE WITNESS: Yes, it is. 4 BY MR. GOSS:	
4 THE WITNESS: Yes, it is. 4 BY MR. GOSS:	AND: Objection.
·	,
	tion of Ethicon's
6 Q. In your investigation, did you find 6 files in review of discovery	
7 that Johnson & Johnson lived up or Ethicon 7 and all the things that w	,
8 lived up to this credo?  8 that you reviewed in ap	
9 MS. SUTHERLAND: Objection. 9 of care and the docume	
· · · · · · · · · · · · · · · · · · ·	•
10 THE WITNESS: I found that they 10 standard of care, did yo	
did not live up to this credo.	
12 BY MR. GOSS: 12 standard of care in its n	
13 Q. With respect to their development 13 MCM, TVT obturator sys	
	AND: Objection.
15 MS. SUTHERLAND: Objection. 15 THE WITNESS	: Yes, I did.
16 THE WITNESS: That is correct. 16 BY MR. GOSS:	
17 BY MR. GOSS: 17 Q. And what is that	opinion?
18 Q. Okay. You've talked a little bit 18 A. They violated the	standard of care
19 about the label. Who is responsible for 19 in several ways.	
20 making sure that the label is accurate? 20 Q. Did you reach an	opinion whether
21 A. The primary responsibility is that 21 Ethicon violated the star	
22 of the manufacturer. 22 failing to conduct appro	
23 Q. And I've heard the concept called 23 support the safe and eff	
24 "owning the label." What's that mean? 24 TVT obturator system?	rective use of the
	AND: Objection.
25 A. Mat the mandracturer it is	AND: Objection:
Page 359	Page 361
1 their product. The manufacturer owns the 1 THE WITNESS	-
2 label. It is a component of the product, in 2 BY MR. GOSS:	
3 this case, the TVT-O. And owning the TVT-O, 3 Q. What is that opin	ion?
4 the company, Ethicon, also owns the label, 4 MS. SUTHERLA	
5 meaning that it is responsible for making 5 objection.	AND. Same
· · · · · · · · · · · · · · · · · · ·	: They failed to
, , , , , , , , , , , , , , , , , , , ,	
1 7 71 3	Standard of Care.
8 its product is truthful and accurate and 8 BY MR. GOSS:	and all an order able and
9 complete and not misleading. 9 Q. Did you reach an	
10 Q. The buck stops with the 10 the labeling for the TVT	obturator system
11 manufacturer? 11 was inadequate?	
12 MS. SUTHERLAND: Objection. 12 A. Yes, I did.	_
13 THE WITNESS: That's correct. 13 Q. Due to failure to	warn?
14 BY MR. GOSS: 14 A. Yes.	I
15 Q. The safety principles that we've 15 Q. What's that opinion	
	AND: Objection.
17 part of the standard of care for a 17 THE WITNESS	: The labeling was
18 manufacturer? 18 inadequate.	
18 manufacturer?18 inadequate.19 MS. SUTHERLAND: Objection.19 BY MR. GOSS:	I.
19 MS. SUTHERLAND: Objection. 19 BY MR. GOSS:	opinion as to
19 MS. SUTHERLAND: Objection. 19 BY MR. GOSS: 20 THE WITNESS: Yes, they are. 20 Q. Did you reach an	
19MS. SUTHERLAND: Objection.19BY MR. GOSS:20THE WITNESS: Yes, they are.20Q. Did you reach an21BY MR. GOSS:21whether the label was face.	
19MS. SUTHERLAND: Objection.19BY MR. GOSS:20THE WITNESS: Yes, they are.20Q. Did you reach an21BY MR. GOSS:21whether the label was factorise.22Q. Would you consider the credo that22A. Yes, I did.	alse or misleading?
19 MS. SUTHERLAND: Objection. 20 THE WITNESS: Yes, they are. 21 BY MR. GOSS: 22 Q. Would you consider the credo that 23 putting patients first, first responsibility 20 Q. Did you reach an 21 whether the label was for the credo that 22 A. Yes, I did. 23 Q. What is that opin	alse or misleading? ion?
19 MS. SUTHERLAND: Objection. 20 THE WITNESS: Yes, they are. 21 BY MR. GOSS: 22 Q. Would you consider the credo that 23 putting patients first, first responsibility 24 to patients, the credo adopted by this 29 BY MR. GOSS: 20 Q. Did you reach an 21 whether the label was for the credo that 22 A. Yes, I did. 23 Q. What is that opin 24 MS. SUTHERLA	alse or misleading?

		Page 362			Page 364
1	false and misleading.		1	THE REPORTER: Excuse me. Did	
2	BY MR. GOSS:		2	you say Exhibit 21?	
3	Q. Did you reach an opinion as to		3	MR. GOSS: You know what? I'm	
4	whether Ethicon failed to meet the		4	sorry. I grabbed the wrong one. I'm	
5	post-market vigilant standard of care in		5	going to re-mark Exhibit 21 as	
6	management of risk?		6	Exhibit 18.	
7	A. Yes, I did.		7	(Exhibit Number 18 was	
			8		
8	Q. What is that opinion?			marked for identification.)	
9	MS. SUTHERLAND: Objection.		9	BY MR. GOSS:	
10	THE WITNESS: They failed to		10	Q. Again, is Exhibit 18 the Exhibit 2	
11	meet the post-market vigilant standard		11	you just referenced?	
12	of care and manage risk appropriately.		12	A. Yes, it is.	
13	BY MR. GOSS:		13	Q. Okay. All the opinions that you've	
14	Q. You have prepared a report in this		14	given today and that you are going to give	
15	case?		15	today, have they all been held to a	
16	A. Yes.		16	reasonable degree of scientific or	
17	Q. Did you prepare a supplemental		17	professional certainty?	
18	report as well?		18	A. Yes, they have.	
19	A. Yes, I did.		19	Q. We've talked a little bit about the	
20	MR. GOSS: Did we mark those		20	TVT-O. What was it designed to treat?	
21	already?		21	A. Stress urinary incontinence.	
22	MS. SUTHERLAND: Yeah.		22	Q. When did it come on the market?	
23	THE WITNESS: I'm not sure		23	<del>-</del>	
				A. The very end of 2003, early 2004.	
24	Exhibit 2 to the March supplemental		24	Q. And was the TVT retropubic already	
25	report was marked.		25	on the market?	
		Dago 262			Dago 26E
1	RV MP. GOSS:	Page 363	1		Page 365
1	BY MR. GOSS:	Page 363	1	A. Yes.	Page 365
2	Q. Is Exhibit 4 the supplemental	Page 363	2	<ul><li>A. Yes.</li><li>Q. Do you recall how long it had been</li></ul>	Page 365
2	Q. Is Exhibit 4 the supplemental report that you prepared in this case?	Page 363	2 3	A. Yes. Q. Do you recall how long it had been on the market?	Page 365
2 3 4	Q. Is Exhibit 4 the supplemental report that you prepared in this case? Pence Exhibit 4.	Page 363	2 3 4	<ul><li>A. Yes.</li><li>Q. Do you recall how long it had been on the market?</li><li>A. Since 1998.</li></ul>	Page 365
2 3 4 5	Q. Is Exhibit 4 the supplemental report that you prepared in this case? Pence Exhibit 4. A. Yes.	Page 363	2 3 4 5	<ul><li>A. Yes.</li><li>Q. Do you recall how long it had been on the market?</li><li>A. Since 1998.</li><li>Q. What type of mesh is used in the</li></ul>	Page 365
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2 3 4 5 6 7	Q. Is Exhibit 4 the supplemental report that you prepared in this case? Pence Exhibit 4. A. Yes. Q. And did that Pence Exhibit 4 supplement Pence Exhibit 3?	Page 363	2 3 4 5 6 7	<ul> <li>A. Yes.</li> <li>Q. Do you recall how long it had been on the market?</li> <li>A. Since 1998.</li> <li>Q. What type of mesh is used in the TVT-O?</li> <li>A. Polypropylene mesh.</li> </ul>	Page 365
2 3 4 5 6 7 8	Q. Is Exhibit 4 the supplemental report that you prepared in this case? Pence Exhibit 4.  A. Yes. Q. And did that Pence Exhibit 4 supplement Pence Exhibit 3? A. Yes.	Page 363	2 3 4 5 6 7 8	A. Yes. Q. Do you recall how long it had been on the market? A. Since 1998. Q. What type of mesh is used in the TVT-O? A. Polypropylene mesh. Q. There's going to be some discussion	Page 365
2 3 4 5 6 7 8 9	Q. Is Exhibit 4 the supplemental report that you prepared in this case? Pence Exhibit 4. A. Yes. Q. And did that Pence Exhibit 4 supplement Pence Exhibit 3? A. Yes. Q. And is Exhibit 6 also a part of	Page 363	2 3 4 5 6 7 8 9	A. Yes. Q. Do you recall how long it had been on the market? A. Since 1998. Q. What type of mesh is used in the TVT-O? A. Polypropylene mesh. Q. There's going to be some discussion today about MCM-cut mesh.	Page 365
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1	Do you know what that is?	1	A. Yes.	
2	A. Yes.	2	Q. And what was that reason?	
3	Q. What is that?	3	MS. SUTHERLAND: Objection. THE WITNESS: The idea was to	
4	A. Laser-cut mesh.	4	reduce the numbers of bladder	
5 6	Q. Are they two different methods of cutting?	5 6		
7	A. Yes.	7	perforations that were occurring. BY MR. GOSS:	
8	Q. Okay. Do you know what type of	8	Q. What was happening in the market?	
9	TVT-O mesh was implanted in Jennifer Ramirez	9	MS. SUTHERLAND: Objection.	
10	on September 17, 2010?	10	THE WITNESS: What was	
11	A. Yes, I do.	11	happening in the market with the TVT-O	
12	Q. What was it?	12	was Ethicon had enjoyed about five years	
13	A. A mechanically cut mesh.	13	of the market for stress urinary	
14	Q. And it was a TVT-O?	14	incontinence slings, and competitors	
15	A. That's correct.	15	were coming on the market, and in	
16	Q. Okay. I'm going to hand you what's	16	particular, a couple of other companies	
17	been marked as Exhibit 19.	17	had marketed devices with an obturator	
18	(Exhibit Number 19 was	18	approach, and that was hoped that it	
19	marked for identification.)	19	would be safer than the retropubic	
20	BY MR. GOSS:	20	approach because of the numbers of	
21	Q. What is that document?	21	bladder perforations in particular that	
22	A. This is a document that has a	22	can occur and have occurred with the	
23	sticker from the TVT-O device that was	23	retropubic approach.	
24	implanted in Ms. Ramirez. The document is a	24	And so in order to retain and	
25	Baptist Health System document dated 9/17/10	25	not lose market share, the company	
	.,,		,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
	Page 367			Page 369
				. age ses
1	showing the surgeon's name, Dr. C. Reyes	1	decided that they needed to enter the	rage 505
1 2	showing the surgeon's name, Dr. C. Reyes or C. Reyes, implant location, vagina.	1 2	decided that they needed to enter the competitive market space with an	r age 303
			competitive market space with an obturator approach.	r age 303
2	or C. Reyes, implant location, vagina.	2	competitive market space with an obturator approach. BY MR. GOSS:	rage 303
2 3 4 5	or C. Reyes, implant location, vagina. Q. Is this one of the documents you relied upon in determining whether or not she was implanted with a mechanically cut	2 3	competitive market space with an obturator approach. BY MR. GOSS: Q. Okay. Let's back it up a little	ruge sos
2 3 4 5 6	or C. Reyes, implant location, vagina. Q. Is this one of the documents you relied upon in determining whether or not she was implanted with a mechanically cut mesh?	2 3 4 5 6	competitive market space with an obturator approach. BY MR. GOSS: Q. Okay. Let's back it up a little bit and let me get some clarification. You	. uge sos
2 3 4 5 6 7	or C. Reyes, implant location, vagina. Q. Is this one of the documents you relied upon in determining whether or not she was implanted with a mechanically cut mesh? A. Yes.	2 3 4 5 6 7	competitive market space with an obturator approach. BY MR. GOSS: Q. Okay. Let's back it up a little bit and let me get some clarification. You said that they had been a market leader for	. uge sos
2 3 4 5 6 7 8	or C. Reyes, implant location, vagina. Q. Is this one of the documents you relied upon in determining whether or not she was implanted with a mechanically cut mesh? A. Yes. Q. And how can you tell by looking at	2 3 4 5 6 7 8	competitive market space with an obturator approach. BY MR. GOSS: Q. Okay. Let's back it up a little bit and let me get some clarification. You said that they had been a market leader for five years.	rege 300
2 3 4 5 6 7 8 9	or C. Reyes, implant location, vagina. Q. Is this one of the documents you relied upon in determining whether or not she was implanted with a mechanically cut mesh? A. Yes. Q. And how can you tell by looking at this document that it was mechanically cut?	2 3 4 5 6 7 8 9	competitive market space with an obturator approach. BY MR. GOSS: Q. Okay. Let's back it up a little bit and let me get some clarification. You said that they had been a market leader for five years. With respect to what product?	rage 300
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2 3 4 5 6 7 8 9 10	or C. Reyes, implant location, vagina. Q. Is this one of the documents you relied upon in determining whether or not she was implanted with a mechanically cut mesh? A. Yes. Q. And how can you tell by looking at this document that it was mechanically cut? A. The number that's on the sticker from the mesh that was implanted, 810081,	2 3 4 5 6 7 8 9 10 11	competitive market space with an obturator approach. BY MR. GOSS: Q. Okay. Let's back it up a little bit and let me get some clarification. You said that they had been a market leader for five years. With respect to what product? A. The TVT retropubic. Q. Not the O?	. ege soo
2 3 4 5 6 7 8 9 10 11 12	or C. Reyes, implant location, vagina. Q. Is this one of the documents you relied upon in determining whether or not she was implanted with a mechanically cut mesh? A. Yes. Q. And how can you tell by looking at this document that it was mechanically cut? A. The number that's on the sticker from the mesh that was implanted, 810081, does not have an L at the end, and when it's	2 3 4 5 6 7 8 9 10 11 12	competitive market space with an obturator approach. BY MR. GOSS: Q. Okay. Let's back it up a little bit and let me get some clarification. You said that they had been a market leader for five years. With respect to what product? A. The TVT retropubic. Q. Not the O? A. That's correct.	. ege soo
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	or C. Reyes, implant location, vagina. Q. Is this one of the documents you relied upon in determining whether or not she was implanted with a mechanically cut mesh? A. Yes. Q. And how can you tell by looking at this document that it was mechanically cut? A. The number that's on the sticker from the mesh that was implanted, 810081, does not have an L at the end, and when it's laser-cut mesh, an L is included at the end of that series of numbers. Q. How did you learn that? A. Through review of the Ethicon documentation. Q. In conducting your investigation into Ethicon's internal documents, were you	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	competitive market space with an obturator approach. BY MR. GOSS: Q. Okay. Let's back it up a little bit and let me get some clarification. You said that they had been a market leader for five years. With respect to what product? A. The TVT retropubic. Q. Not the O? A. That's correct. Q. Okay. And were competitors entering the market? A. Yes. Q. Did you see any documents that reflected that Ethicon was concerned about the competitors entering the market? A. Yes, I did.	. age 300
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	or C. Reyes, implant location, vagina. Q. Is this one of the documents you relied upon in determining whether or not she was implanted with a mechanically cut mesh? A. Yes. Q. And how can you tell by looking at this document that it was mechanically cut? A. The number that's on the sticker from the mesh that was implanted, 810081, does not have an L at the end, and when it's laser-cut mesh, an L is included at the end of that series of numbers. Q. How did you learn that? A. Through review of the Ethicon documentation. Q. In conducting your investigation into Ethicon's internal documents, were you able to determine the reason Ethicon developed the TVT-O?  MS. SUTHERLAND: Objection. THE WITNESS: The TVT-O? BY MR. GOSS:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	competitive market space with an obturator approach. BY MR. GOSS: Q. Okay. Let's back it up a little bit and let me get some clarification. You said that they had been a market leader for five years. With respect to what product? A. The TVT retropubic. Q. Not the O? A. That's correct. Q. Okay. And were competitors entering the market? A. Yes. Q. Did you see any documents that reflected that Ethicon was concerned about the competitors entering the market? A. Yes, I did. MS. SUTHERLAND: Objection. BY MR. GOSS: Q. I'm handing you what's been marked as Exhibit 20. (Exhibit Number 20 was	. age 300
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	or C. Reyes, implant location, vagina. Q. Is this one of the documents you relied upon in determining whether or not she was implanted with a mechanically cut mesh? A. Yes. Q. And how can you tell by looking at this document that it was mechanically cut? A. The number that's on the sticker from the mesh that was implanted, 810081, does not have an L at the end, and when it's laser-cut mesh, an L is included at the end of that series of numbers. Q. How did you learn that? A. Through review of the Ethicon documentation. Q. In conducting your investigation into Ethicon's internal documents, were you able to determine the reason Ethicon developed the TVT-O?  MS. SUTHERLAND: Objection. THE WITNESS: The TVT-O?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	competitive market space with an obturator approach. BY MR. GOSS: Q. Okay. Let's back it up a little bit and let me get some clarification. You said that they had been a market leader for five years. With respect to what product? A. The TVT retropubic. Q. Not the O? A. That's correct. Q. Okay. And were competitors entering the market? A. Yes. Q. Did you see any documents that reflected that Ethicon was concerned about the competitors entering the market? A. Yes, I did. MS. SUTHERLAND: Objection. BY MR. GOSS: Q. I'm handing you what's been marked as Exhibit 20.	. age 300

		Page 370			Page 372
1	BY MR. GOSS:		1	you've seen in this document where it	
2	Q. Is that a document that you		2	reflects that their concern was trying to	
3	discovered in Ethicon's files?		3	develop a better product for their patients?	
4	MS. SUTHERLAND: Objection.		4	MS. SUTHERLAND: Objection.	
5	THE WITNESS: Yes.		5	MR. GOSS: Let me re-ask that.	
6	BY MR. GOSS:		6	BY MR. GOSS:	
7	Q. And is this a document that you		7	Q. Under this strategic rationale,	
8	relied upon in forming your opinions in this		8	does it discuss how much they thought they	
9	case?		9	would lose if they if things continued as	
10	A. Yes.		10	they were with the TVT franchise?	
11	Q. And what's the date of this		11	MS. SUTHERLAND: Objection.	
12	document?		12	THE WITNESS: Yes, it does.	
13	A. 14 February, 2003.		13	BY MR. GOSS:	
14	Q. And the document's regarding		14	Q. What was that?	
15	Project Mulberry.		15	A. It was \$8 million, if I recall	
16	What is that?		16	correctly, yes.	
17	A. Project Mulberry was the project		17	Q. Under the financial summary, does	
18	name given to the development of TVT-O.		18	it reflect how much they thought they could	
19	Q. And let's just start with the		19	profit if they launched a product like the	
				TVT-O?	
20	executive summary and the strategic		20		
21	rationale. Is there anything under		21	MS. SUTHERLAND: Objection.	
22	strategic rationale with respect to this		22	THE WITNESS: Yes, it does.	
23	document that you found important in your		23	BY MR. GOSS:	
24	opinions today?		24	Q. What did they project as year of	
25	A. Yes.		25	sales of TVT-O?	
		Page 371			Page 373
1	Q. What's that?	Page 371	1	MS. SUTHERLAND: Objection.	Page 373
2	A. The rationale that we were just	Page 371	1 2	THE WITNESS: I'm sorry?	Page 373
2	A. The rationale that we were just discussing for development of the TVT-O	Page 371	2	THE WITNESS: I'm sorry? BY MR. GOSS:	Page 373
2	A. The rationale that we were just	Page 371	2	THE WITNESS: I'm sorry?	Page 373
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2 3 4	A. The rationale that we were just discussing for development of the TVT-O being competitive pressure.  Q. It says, "The rationale for Project	Page 371	2 3 4	THE WITNESS: I'm sorry? BY MR. GOSS: Q. By 2010, were they projecting	Page 373
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1		Page 374			Page 376
1	they could have products sales exceeding	age 57 i	1	The document speaks for itself.	ruge 370
1					
2	34 million by 2010?		2	THE WITNESS: Three things.	- 1
3	MS. SUTHERLAND: Objection.		3	That it's a new procedure. Secondly,	
4	THE WITNESS: Correct.		4	the obturator bundle because, again, if	
5	BY MR. GOSS:		5	I might explain that, the insertion	
6	Q. Okay. Let's go to the second page.		6	route is a different route, and in the	
7	I'm going to ask you about the first line of		7	obturator bundle, they're the obturator	
8	that second page. It says, "The assumptions		8	nerve and obturator vessels which, if	- 1
9			9	those are perforated, could cause	
	used to make product sales forecasts are as			· · · · · · · · · · · · · · · · · · ·	
10	follows: U.S. assumes introduction of		10	issues, safety issues, for the patient,	
11	Mulberry in quarter 1 2005 after six months		11	present potential risks.	
12	of clinical data is available."		12	And the third is future, as	
13	What does that mean?		13	they term it, radical developments, for	
14	MS. SUTHERLAND: Objection.		14	example, needle-less TVT and growth	
15	THE WITNESS: That means at the		15	factors.	
16	time this document was prepared in		16	BY MR. GOSS:	
17	February of 2003, that the company		17	Q. So in 2003, just so I'm clear, is	
18	intended to introduce TVT-O once they		18	Ethicon evaluating already under risk	
19	had six months of clinical testing data		19	assessment, clinical issues and risks with	- 1
20	available.		20	the obturator bundle?	
21	BY MR. GOSS:		21	MS. SUTHERLAND: Objection.	
22	Q. Is that a good thing?		22	THE WITNESS: Yes.	
23	MS. SUTHERLAND: Objection.		23	BY MR. GOSS:	
24	THE WITNESS: That's a good		24	Q. Do you find that important?	
25			25	A. Yes.	
23	thing, yes.		23	A. Tes.	
		D 27F			D 277
_		Page 375			Page 377
			4	O 14/h, 2	
1	BY MR. GOSS:		1	Q. Why?	
2	Q. Is that what you would expect a		2	A. Because those risks in order it	
2	Q. Is that what you would expect a company I'm sorry.		2 3	A. Because those risks in order it goes back to what I may have talked about	
2	Q. Is that what you would expect a		2	A. Because those risks in order it	
2	Q. Is that what you would expect a company I'm sorry.		2 3	A. Because those risks in order it goes back to what I may have talked about	
2 3 4 5	Q. Is that what you would expect a company I'm sorry. Is that what you would expect a		2 3 4	A. Because those risks in order it goes back to what I may have talked about already today that before marketing a product, one needs to do a benefit/risk	
2 3 4 5 6	Q. Is that what you would expect a company I'm sorry.  Is that what you would expect a design a device company let me start over.		2 3 4 5 6	A. Because those risks in order it goes back to what I may have talked about already today that before marketing a product, one needs to do a benefit/risk assessment to assure that there's a	
2 3 4 5 6 7	Q. Is that what you would expect a company I'm sorry.  Is that what you would expect a design a device company let me start over.  Is that what you would expect a		2 3 4 5 6 7	A. Because those risks in order it goes back to what I may have talked about already today that before marketing a product, one needs to do a benefit/risk assessment to assure that there's a favorable benefit/risk ratio, and that	
2 3 4 5 6 7 8	Q. Is that what you would expect a company I'm sorry.  Is that what you would expect a design a device company let me start over.  Is that what you would expect a device manufacturer to do?		2 3 4 5 6 7 8	A. Because those risks in order it goes back to what I may have talked about already today that before marketing a product, one needs to do a benefit/risk assessment to assure that there's a favorable benefit/risk ratio, and that includes an assessment of potential risks,	
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Is that what you would expect a company I'm sorry.    Is that what you would expect a design a device company let me start over.    Is that what you would expect a device manufacturer to do?    A. Absolutely.    Q. To conduct six months clinical data?    A. Minimally six months.    Q. Okay. We'll get to this a little bit later. Did they do that?    A. No, they did not. Not beyond what the inventor of the product had already done with the prototype.    Q. Let's go to the Bates number on that exhibit that is it's page 7. Bates number ends at 53.    Do you see "Risk Assessment"?    A. Yes.		2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. Because those risks in order it goes back to what I may have talked about already today that before marketing a product, one needs to do a benefit/risk assessment to assure that there's a favorable benefit/risk ratio, and that includes an assessment of potential risks, and the way you assess that risk is through clinical testing.  Q. Did in your investigation of the files of Ethicon, did you see anywhere where they where it upset where it assessed the risk of obturator bundle injury prior to launching this product?  A. No. Certainly not in clinical testing.  Q. Would a reasonable and prudent manufacturer have done that assessment?  MS. SUTHERLAND: Objection.  THE WITNESS: Yes.  (Exhibit Number 21 was	

	•	Page 378			Page 380
1	marked as Pence Exhibit 21. And is this a		1	Again, what's Mulberry?	
2	document that you reviewed first of all,		2	A. That's the project name for the	
3			3	TVT-O.	
	did you find this in Ethicon's files?				
4	MS. SUTHERLAND: Objection.		4	Q. "Can you please clarify whether or	
5	THE WITNESS: Yes.		5	not post-market introduction studies are	
6	BY MR. GOSS:		6	acceptable or not? If we only have ex-U.S.	
7	Q. Is this a document that you		7	data, won't this limit us? Brian."	
8	reviewed and relied upon in coming up with		8	Was this document was that email	
9	your opinions in this case?		9	important for your opinions?	
10	A. Yes, it is.		10	MS. SUTHERLAND: Objection.	
11	Q. Is this document dated April 14,		11	The document speaks for itself.	
12	2003?		12	THE WITNESS: Yes.	
13	A. Yes, it is.		13	BY MR. GOSS:	
			14		
14	Q. Is this an Ethicon document?			Q. Why?	
15	A. Yes.		15	A. Because as the risk assessment	
16	Q. Came out of their files?		16	noted in the document we just reviewed,	
17	MS. SUTHERLAND: Objection.		17	Exhibit 20, the there are risks with a	
18	THE WITNESS: That's correct.		18	new procedure, risks with the obturator	
19	BY MR. GOSS:		19	approach, particularly with regard to the	
20	Q. Is Brian I believe Brian		20	obturator bundle, and clinical testing in	
21	Luscombe, is he the U.S. products director?		21	February of 2003 was intended to be done.	
22	A. Yes. To the best of my		22	And in this document, we learn two	
23	recollection, that is correct.		23	months later, almost two months later to the	
24	Q. And he's on this email string.		24	date, that the Gynecare board had made the	
25	This is a long email string; right?		25	decisions the decision that clinicals	
		Page 379			Page 381
1	A Yes it is	Page 379	1	would not be done which means that these	Page 381
1 2	A. Yes, it is.  O As I understand, the way that you	Page 379	1 2	would not be done, which means that these	Page 381
2	Q. As I understand, the way that you	Page 379	2	risks would not be assessed in human testing	Page 381
2	Q. As I understand, the way that you read these documents out of their files that	Page 379	2 3	risks would not be assessed in human testing prior to marketing.	Page 381
2 3 4	Q. As I understand, the way that you read these documents out of their files that are email strings is you start from the back	Page 379	2 3 4	risks would not be assessed in human testing prior to marketing.  Q. Is that decision by the Gynecare	Page 381
2 3 4 5	Q. As I understand, the way that you read these documents out of their files that are email strings is you start from the back and work your way forward; is that correct?	Page 379	2 3 4 5	risks would not be assessed in human testing prior to marketing. Q. Is that decision by the Gynecare board in violation of standards in the	Page 381
2 3 4 5 6	Q. As I understand, the way that you read these documents out of their files that are email strings is you start from the back and work your way forward; is that correct?  A. Correct.	Page 379	2 3 4 5 6	risks would not be assessed in human testing prior to marketing.  Q. Is that decision by the Gynecare board in violation of standards in the industry?	Page 381
2 3 4 5 6 7	Q. As I understand, the way that you read these documents out of their files that are email strings is you start from the back and work your way forward; is that correct?  A. Correct.  Q. So let's do that. So start at the	Page 379	2 3 4 5 6 7	risks would not be assessed in human testing prior to marketing. Q. Is that decision by the Gynecare board in violation of standards in the industry?  MS. SUTHERLAND: Objection.	Page 381
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		1		
	Page 382			Page 384
1	right following this one.	1	Q. Should a company ever put market	
2	A. Okay.	2	share and profits over safety?	
3	Q. Okay. So to set the stage to	3	MS. SUTHERLAND: Objection.	
4	set the stage, we know two months ago there	4	THE WITNESS: Never.	
5	was a projection that there would be a six	5	BY MR. GOSS:	
6	months of clinicals done before launch.	6	Q. Is that a violation of the industry	
7	MS. SUTHERLAND: Objection.	7	standards?	
8	THE WITNESS: That's correct.	8	MS. SUTHERLAND: Objection.	
9	BY MR. GOSS:	9	THE WITNESS: Yes, it is.	
10	Q. And then we have an email here	10	///	
11	where we learn and you learn in your	11	BY MR. GOSS:	
12	investigation that the Gynecare board made	12	Q. Would that be a violation of	
13	the decision that they weren't going to do	13	Ethicon's own credo?	
14	the clinical testing.	14	MS. SUTHERLAND: Objection.	
15	MS. SUTHERLAND: Objection.	15	THE WITNESS: Yes, it is.	
16	THE WITNESS: That's correct.	16	BY MR. GOSS:	
17	BY MR. GOSS:	17	Q. Would that be a violation of the	
18	Q. Okay. So let's get to the next	18	Global Harmonization Task Force?	
19	email. Cheryl Bogardus, I assume she was	19	MS. SUTHERLAND: Objection.	
20	the same Cheryl from below; right?	20	THE WITNESS: Yes, it would.	
21	A. Yes.	21	(Exhibit Number 22 was	
22	Q. Writing back to Brian Luscombe,	22	marked for identification.)	
23	responding to the previous email, she	23	BY MR. GOSS:	
24	says let's get to the second sentence in	24	Q. I'll hand you what's been marked as	
25	the second paragraph. "To protect our	25	Pence Exhibit 22.	
	2 222			
	Page 383		To the to do a magnet that you found	Page 385
1	market share, we need to be ready to launch.	1	Is that a document that you found	Page 385
2	market share, we need to be ready to launch. So the development process should not	2	in Ethicon's files?	Page 385
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		Page 386			Page 388
1	Bogardus, we just spoke about her. Is she	i age Joo	1	to safety?	. agc 300
2	the worldwide marketing director?		2		
3	A. Yes. That's my understanding, yes.		3	MS. SUTHERLAND: Objection. THE WITNESS: No.	
4	Q. What about Axel Arnaud? I see he		4	BY MR. GOSS:	
5	is cc'd. Who's that?		5	Q. Did you ever see any documents that	
6	A. He was actually for the TVT-O,		6	reflected how much the French market was	
7	he was actually the person who identified		7	estimated to lose as a result of the	
8	the Dr. De Leval who is the inventor of		8	competitors entering the market in the TVT?	
9	the in-out procedure that is the TVT-O		9	A. Yes.	
10	procedure.		10	Q. What percentage of the market were	
11	Q. Was he the head of medical affairs?		11	they anticipating losing?	
12	A. In Europe, yes.		12	A. If I recall correctly, it was	
13	Q. Okay. This document says, "Dear		13	30 percent.	
14	All, as you know, Project Mulberry"		14	Q. Is that substantial for a	
15	again, is that the TVT-O?		15	manufacturer?	
16	A. Yes.		16	MS. SUTHERLAND: Objection.	
17	Q "is critical to Gynecare's		17	THE WITNESS: Yes.	
18	success in the incontinence marketplace.		18	MR. GOSS: I'm sorry. I only	
19	This team has been charged with the		19	have one copy, but I think you've seen	
				* * * * * * * * * * * * * * * * * * * *	
20	breakthrough goal of completing this project		20	it.	
21	within nine months. We must make this		21	MS. SUTHERLAND: It's not like	
22	project happen in a short period of time.		22	I have a whole lot of time when you get	
23	You play a critical role in bringing this		23	done to ask questions about it.	
24	endeavor."		24	MR. GOSS: Yeah.	
25	First of all, do you find that		25	BY MR. GOSS:	
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		Page 387			Page 389
1	important	Page 387	1	Q. I'm going to hand you what's been	Page 389
1 2	important MS. SUTHERLAND: Objection.	Page 387	1 2	Q. I'm going to hand you what's been marked as Exhibit 23.	Page 389
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		Page 390			age 392
1	this product.		1	Number 9, for example, says, "Since	
2	Q. Okay. And is the product on the		2	the needles don't enter the retropubic	
3	market yet?		3	space, bladder perforation should be	
4	A. It was launched in this period of		4	reduced."	
5	time. It was cleared to go to the market in		5	That's what you said earlier?	
6	December of 2003. So this is this is		6	A. That's correct.	
7	the		7	Q. It's a good scientific reason?	
8	Q. The TVT-O?		8	A. Yes, it is.	
9	A. The TVT-O:  A. The TVT-O: This is the sales		9	Q. Says one of the inventors, number	
				- ,	
10	training right after the product was cleared		10	4, "Doesn't like the obturator approach."	
11	so that it could be sold in the U.S.		11	That's a competitor doesn't like	
12	Q. Okay. And is this a PowerPoint?		12	it; right?	
13	A. Yes.		13	A. Yes.	
14	Q. Okay. And, again, they're using		14	Q. Number 5, it says, "The hammock	
15	this to train their sales team?		15	shape of the sling may result in less	
16	A. Yes.		16	obstructive symptoms since it's hard to	
17	Q. Okay. Let's turn to the pages		17	over-compress the urethra with the obturator	
18	aren't numbered, but can you find the top		18	sling."	
19	ten reasons to pursue the TVT obturator		19	Scientific reason?	
20	approach.		20	A. Yes. Medical reason, yes.	
21	A. Sorry. Some of them are upside		21	Q. And what did they give as the	
22	down. I'm trying to find them.		22	number one reason as to why they should	
23	Q. Let me find it for you.		23	pursue the TVT obturator approach?	
24	By the way, did you review this		24	MS. SUTHERLAND: Objection.	
25	document in preparation for your opinions?		25	THE WITNESS: "Mama needs a new	
	document in preparation for your opinions.		23	THE WITNESS. Flama needs a new	
		Page 391		Pa	age 393
1	A. I did.	Page 391	1	Pa pair of shoes."	age 393
1 2	A. I did. MS. SUTHERLAND: I'll object	Page 391	1 2		age 393
2	MS. SUTHERLAND: I'll object	Page 391		pair of shoes." BY MR. GOSS:	age 393
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Page 396 Page 394 or, where applicable, other persons provided 1 6:29 p.m. to 6:36 p.m.) 1 2 THE VIDEOGRAPHER: With the 2 that any risks which may be associated with 3 approval of counsel, back on the record. their use constitute acceptable risks when 3 4 The time is approximately 6:36 p.m. 4 weighed against the benefits of the patient 5 5 and are compatible with a high level of BY MR. GOSS: 6 6 protection of health and safety." Q. Dr. Pence, I should have done this 7 early on. I'll go ahead and do it now. We 7 That's a long way of saying --8 8 isn't it? -- that manufacturers should keep talking about the Global Harmonization 9 Task Force, and we spent a lot of time on 9 market safe products? 10 that this morning, and I'm not sure if this 10 MS. SUTHERLAND: Objection. 11 has been marked, but I'm going to mark 11 THE WITNESS: Safe, and as I mentioned before, that have a favorable 12 another one just in case. 12 I've marked Pence Exhibit 24. 13 13 benefit-to-risk ratio. 14 (Exhibit Number 24 was 14 BY MR. GOSS: marked for identification.) 15 15 Q. Okay. I got on objection. Let me 16 BY MR. GOSS: 16 try to fix this. 17 Q. So I've handed you what has been 17 What are they saying there in 18 marked as Pence Exhibit 24. And when we've 18 Section 5.1? talked about the Global Harmonization Task A. They're saying that for the 19 19 20 Force, is this one of the documents we 20 intended use of a medical device, that they talked about? should be designed and produced in such a 21 21 22 A. Yes, it is. 22 way that for their intended use, they don't compromise -- they don't cause undue risk to 23 Q. Its title is "Essential Principles 23 24 of Safety and Performance of Medical 24 the patient or users of the device either Devices," endorsed by the Global and that, again, as I've specified before, 25 25 Page 395 Page 397 Harmonization Task Force dated May 20, 2005. 1 that one has to always look at the potential 1 2 2 risks versus the potential benefits and A. That's correct. 3 Q. And this is one of the documents 3 assure that there's a favorable 4 that you discussed previously that provides 4 benefit-to-risk ratio. 5 the standard of care with respect to device 5 In other words, that the benefits 6 manufacturers? 6 exceed the potential risks and any risks are 7 A. Yes. It is an international 7 acceptable. 8 8 standard of care. Q. We talked about safety principles 9 Q. Okay. And this is something that 9 earlier in Exhibit 16. 10 you applied in giving your opinions? 10 A. Yes. 11 A. Yes. Q. Does that support your safety 11 12 O. Okay. Let's go to page 8 of that 12 principle number 1? document. Go to page 8 of that document and 13 13 MS. SUTHERLAND: Objection. talking about under a section called 14 14 THE WITNESS: Yes. 15 "Essential Principles of Safety and 15 BY MR. GOSS: Performance of Medical Devices." It says, Q. Like the first line, "A corporation 16 16 "General Requirements. Medical devices is required to make sure its products are 17 17 18 should be designed and manufactured in such 18 reasonably safe"? a way that, when used under the conditions 19 19 A. Yes. and for the purposes intended, and where 20 20 MS. SUTHERLAND: Objection. applicable, by virtue of the technical 21 21 BY MR. GOSS: 22 knowledge, experience, education or training 22 O. Does it also support "Safety of of intended users, they will not compromise patients has to be the number one priority, 23 23 the clinical condition or the safety of 24 24 not corporate profits"? patients or the safety and health of users 25 A. Yes, it does. 25

Page 398 Page 400 A. Yes. 1 MS. SUTHERLAND: Objection. 1 2 BY MR. GOSS: 2 O. What does that mean? 3 3 Q. Let me ask you -- let's go down A. That means in the design of the 4 that document some more. 4 device and how it's actually produced, that 5 5 they do a risk assessment and anything that MS. SUTHERLAND: Can I have a 6 6 they can do to control risks in how the continuing objection, again, to just 7 reading the GHTF documents as well as 7 device is designed and manufactured, they 8 you already gave me the one on the 8 are supposed to do. Ethicon documents. 9 9 Q. Does that support, back to Exhibit 16, safety principles, the safety 10 MR. GOSS: Sure. 10 11 How am I supposed to use it if 11 principle on page 3 of Exhibit 16, "If a corporation has two products that treat the 12 I can't read it? Am I supposed to --12 mental telepathy to the -same condition, and one is safer for the 13 13 MS. SUTHERLAND: You're 14 14 patients, the corporation must choose the supposed to ask her what it means if it safest product"? 15 15 needs explanation by an expert. MS. SUTHERLAND: Objection. 16 16 17 BY MR. GOSS: THE WITNESS: Yes. That would 17 18 Q. Let talk about Section 5.2 of the 18 be consistent with what we just read. general requirements, and I'll ask the court 19 19 BY MR. GOSS: 20 to let us publish 5.2 to the jury. 20 Q. Okay. I'm going to hand you what's 21 Tell me what 5.2 means. 21 been marked as Exhibit 25. 22 A. The essence of this is that a 22 (Exhibit Number 25 was 23 medical device manufacturer must do a risk 23 marked for identification.) assessment of its product to, again, make 24 MS. SUTHERLAND: I've seen it. 24 sure that the risks are acceptable for 25 25 BY MR. GOSS: Page 399 Page 401 the -- how the product is designed and how 1 Q. Is this, again, another Global 1 2 Harmonization Task Force document? 2 it's manufactured, and to do that, they have to identify known or foreseeable potential A. Yes. 3 3 risks, estimate those risks, eliminate them Q. Titled "Clinical Evaluation"? 4 4 5 as far as they can, reduce any remaining 5 A. That's correct. 6 risks by taking adequate protection measures 6 Q. Dated May, 2007? 7 and very importantly, according to what 7 A. That's correct. 8 we've been discussing with regard to 8 Q. Is this one of the documents that 9 labeling, the key there is inform users of 9 you relied upon for the standard of care? 10 any residual risks. 10 A. Yes. Q. Does that support the second page Q. Let me turn you to -- direct you to 11 11 page 4 of 28. And you talked a little bit 12 of your safety principles in Exhibit 16 that 12 a corporation must investigate warning signs earlier about clinical evaluation. 13 13 that its products may be dangerous and make 14 14 A. Yes. 15 sure that any problems with the product are 15 Q. And what does this tell us in that fixed in a safe manner? third section, third paragraph there about 16 16 MS. SUTHERLAND: Objection. clinical evaluation as far as the standard 17 17 18 THE WITNESS: Yes, it does. 18 of care is described in this document? MS. SUTHERLAND: Objection. 19 BY MR. GOSS: 19 20 Q. Okay. Now I'd like for you to look 20 THE WITNESS: Are you talking at page 9 of 15 on that exhibit, which is about the first paragraph after "Why is 21 21 Exhibit 24. In particular, where it says clinical evaluation important?" 22 22 that "They should eliminate risks as far as BY MR. GOSS: 23 23 reasonably practicable through inherently 24 24 O. Right. 25 safe design and manufacture." 25 A. Clinical evaluation is one of the

		Page 402			Page 404
1	methods by which one assures that a device		1	received 510(k) clearance represent that its	
2	satisfies the essential principles of safety		2	product has received approval?	
3	and performance. Basically, it's through		3	A. No.	
4	clinical testing that you determine whether		4	Q. Why is that?	
5	the product is safe and whether it's		5	A. There's a specific regulation that	
6	effective in humans.		6	specifies that one cannot give infer that	
7	Q. Okay. And does it talk about		7	a 510(k) clearance constitutes an approval	
8	minimizing adverse events?		8	by FDA.	
9	A. Yes, it does. And clinical		9	Q. What type of studies are typically	
10	evaluation, in this context, includes		10	done with PMA approval?	
11	clinical data from different sources.		11	A. Almost all PMAs require clinical	
12	Clinical testing as well as commercial		12	human testing.	
13	experience and also the scientific and		13	Q. Okay. But a product a device	
14	medical literature, the peer-reviewed		14	that's gone through 510(k) clearance have	
15	publications that we talked about.		15	done any clinical testing?	
16	Q. Okay. Let's shift gears. Let's go		16	MS. SUTHERLAND: Objection.	
17	to I want to talk with you briefly about		17	THE WITNESS: Only about 10 to	
18	the 510(k) process.		18	15 percent require clinical testing.	
19	What are the two processes by which		19	BY MR. GOSS:	
20	a medical device can come to market?		20	Q. If a manufacturer wanted to do	
21	A. The 510(k) process, if an		21	clinical testing before seeking 510(k)	
22	application is required to be submitted to		22	clearance, could it?	
23	the FDA, either a what's called a 510(k),		23	A. Absolutely.	
24	a pre-market notification, or a pre-market		24	Q. Okay. How long does it take to get	
25	approval application, which is referred to		25	pre-market approval versus clearance?	
23	approval application, which is referred to		23	pre-market approvar versus clearance:	
		Page 403			Page 405
1	as a PMA.	Page 403	1	MS. SUTHERLAND: Objection.	Page 405
1 2	as a PMA. Q. What's the difference between a	Page 403	1 2	MS. SUTHERLAND: Objection. THE WITNESS: The average	Page 405
		Page 403			Page 405
2	Q. What's the difference between a	Page 403	2	THE WITNESS: The average	Page 405
2	Q. What's the difference between a 510(k) pre-market notification or clearance	Page 403	2	THE WITNESS: The average the typically well, it depends on	Page 405
2 3 4	Q. What's the difference between a 510(k) pre-market notification or clearance and pre-market approval?	Page 403	2 3 4	THE WITNESS: The average the typically well, it depends on the type of submission. In the case of TVT-O, it's what we call a special	Page 405
2 3 4 5	Q. What's the difference between a 510(k) pre-market notification or clearance and pre-market approval?  A. There are a number of differences	Page 403	2 3 4 5	THE WITNESS: The average the typically well, it depends on the type of submission. In the case of	Page 405
2 3 4 5 6	Q. What's the difference between a 510(k) pre-market notification or clearance and pre-market approval?  A. There are a number of differences between the two. Probably the key one is	Page 403	2 3 4 5 6	THE WITNESS: The average the typically well, it depends on the type of submission. In the case of TVT-O, it's what we call a special 510(k), and it was approved in	Page 405
2 3 4 5 6 7	Q. What's the difference between a 510(k) pre-market notification or clearance and pre-market approval?  A. There are a number of differences between the two. Probably the key one is that a 510(k) pre-market notification is	Page 403	2 3 4 5 6 7	THE WITNESS: The average the typically well, it depends on the type of submission. In the case of TVT-O, it's what we call a special 510(k), and it was approved in approximately a month, just under a	Page 405
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2 3 4 5 6 7 8 9	Q. What's the difference between a 510(k) pre-market notification or clearance and pre-market approval?  A. There are a number of differences between the two. Probably the key one is that a 510(k) pre-market notification is submitted to FDA to get a clearance of the product to market based on substantial	Page 403	2 3 4 5 6 7 8 9	THE WITNESS: The average the typically well, it depends on the type of submission. In the case of TVT-O, it's what we call a special 510(k), and it was approved in approximately a month, just under a month. The overall average, depending on which year you look at, is around 90	Page 405
2 3 4 5 6 7 8 9	Q. What's the difference between a 510(k) pre-market notification or clearance and pre-market approval?  A. There are a number of differences between the two. Probably the key one is that a 510(k) pre-market notification is submitted to FDA to get a clearance of the product to market based on substantial equivalence to what is termed a predicate	Page 403	2 3 4 5 6 7 8 9	THE WITNESS: The average the typically well, it depends on the type of submission. In the case of TVT-O, it's what we call a special 510(k), and it was approved in approximately a month, just under a month. The overall average, depending on which year you look at, is around 90 to 140 days.	Page 405
2 3 4 5 6 7 8 9 10	Q. What's the difference between a 510(k) pre-market notification or clearance and pre-market approval?  A. There are a number of differences between the two. Probably the key one is that a 510(k) pre-market notification is submitted to FDA to get a clearance of the product to market based on substantial equivalence to what is termed a predicate product, a product that's already legally on	Page 403	2 3 4 5 6 7 8 9 10 11	THE WITNESS: The average the typically well, it depends on the type of submission. In the case of TVT-O, it's what we call a special 510(k), and it was approved in approximately a month, just under a month. The overall average, depending on which year you look at, is around 90 to 140 days. The pre-market approval review	Page 405
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1 MS. SUTHERLAND: Objection. 3 BY MR. GOSS: 4 Q. Is there any room for debate about that? 5 A. No. 8 BY MR. GOSS: 8 BY MR. GOSS: 9 A. No. 9 C. Let's talk a little bit about the TVT-O. And you talked a little bit this 10 unravelling of the tape occurred, and three was some discussion about 13 fraying. 10 Do you recall that? 11 morning with defense counsel about Prolene mesh; and there was some discussion about 13 fraying. 12 A. Yes, I do. 13 Q. In your investigations of in you investigation of Ethicon's files, did you uncover any documents that discussed any complaints about the Prolene mesh product 20 fraying? 21 A. Yes, I did. 22 Q. Did you uncover any documents that discussed particle loss with respect to Prolene mesh? 23 discussed particle loss with respect to Prolene mesh? 24 A. Yes, I did. 25 Q. Did you review any documents that discussed the difference between MCM and LCM 3 with respect to fraying and particle loss? 4 A. Yes, I did. 5 Q. Did you review any documents that discussed the difference between MCM and LCM 3 with respect to fraying and particle loss? 4 A. Yes, I did. 5 Q. Did those documents form a basis of your opinions that you're giving today? 5 A. Yes, Lidi. 6 Q. I'm going to hand you what's been marked as Pence Exhibit 26. 7 MS. SUTHERLAND: Objection. 8 BY MR. GOSS: 9 Q. I believe it's a women's division  1 Q. Did you review any documents that to the product based upon the mesh construction." 10 MS. SUTHERLAND: Objection. 11 The WITNESS: This is a document relating to any the mesh construction." 11 (Exhibit Number 26 was marked for identification.) 12 The WITNESS: The way the product is designed and with the mechanical cutting, what occurs is that there is the term that has been used the reviewed from Ethicon's files? 15 A. Yes, it is. 16 Q. What's the date of this document? 17 Cord based and the time of the mesh in the product is the structure particularly when they—there's particularly when they—there's particularly when they—there's particularly when they—there's particularly when t		557			
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3 BY MR. GOSS: 4 Q. Is there any room for debate about that? 5 A. No. 6 A. No. 7 MS. SUTHERLAND: Objection. 8 BY MR. GOSS: 9 Q. Left stalk a little bit about the 10 TVT-O. And you talked a little bit this 11 morning with defense counsel about Prolene 12 mesh, and there was some discussion about 12 misplantation of the TVT device, the staff found remaining particles that habe been shared from the mesh in the box. 13 fraying. 14 Do you recall that? 15 A. Yes, I do. 16 Q. In your investigations of in your investigation of Ethicon's files, did you uncover any documents that discussed any complaints about the Prolene mesh product 20 fraying? 19 A. Yes, I did. 20 Did you uncover any documents that discussed particle loss with respect to Prolene mesh? 21 A. Yes, I did. 22 Q. Did you uncover any documents that discussed the difference between MCM and LCM 3 with respect to fraying and particle loss? 4 A. Yes, I did. 5 Q. Did those documents form a basis of your opinions that you're giving today? 7 A. Yes, I they did. 8 Q. I'm going to hand you what's been marked as Pence Exhibit 26. 9 Uniform marked as Pence Exhibit 26. 10 /// 11 (Exhibit Number 26 was marked for identification.) 12 marked for identification.) 13 BY MR. GOSS: 14 Q. Is that a document that you reviewed from Ethicon's files? 15 A. Yes, It is. 16 Q. And is this a document? 17 Q. And is this a document? 18 profile a particle loss even without stretching but when particularly when the y there's parduct user.	1	MS. SUTHERLAND: Objection.	1	and TVT-O, do they use the same mesh?	
3 BY MR. GOSS: 4 Q. Is there any room for debate about that? 5 A. No. 6 A. No. 7 MS. SUTHERLAND: Objection. 8 BY MR. GOSS: 9 Q. Left stalk a little bit about the 10 TVT-O. And you talked a little bit this 11 morning with defense counsel about Prolene 12 mesh, and there was some discussion about 13 fraying. 13 Faying. 14 Do you recall that? 15 A. Yes, I do. 16 Q. In your investigations of — in 17 your investigation of Ethicon's files, did 18 you uncover any documents that discussed any complaints about the Prolene mesh product of fraying? 19 A. Yes, I did. 20 Did you uncover any documents that discussed particle loss with respect to 14 discussed the difference between MCM and LCM 24 A. Yes, I did. 19 Q. Did you review any documents that discussed the difference between MCM and LCM 34 with respect to fraying and particle loss? 10 Q. Did those documents form a basis of your opinions that you're giving today? 11 (Exhibit Number 26 was marked for identification.) 12 BY MR. GOSS: 13 Q. Okay. So what is this document, 4 and why was it important to you? 15 MS. SUTHERLAND: Objection. 17 HE WITNESS: This is a document with a focument sher there was unravelling of the tape occurred, and the tape became particles, and after implantation of the TVT device, the staff found remaining particles that habe been lost from the mesh in the box. 16 Q. And Carol — this is a letter from Carol Holloway. She is a product complaint analyst worldwide customer quality for Gyorecare. 17 Q. Did you review any documents that discussed the difference between MCM and LCM and it is discussed the difference between MCM and LCM and it is discussed the difference between MCM and LCM and it is discussed the difference between MCM and LCM and it is discussed the difference between MCM and LCM and it is discussed the difference between MCM and LCM and it is discussed the difference between MCM and LCM and it is discussed the difference between MCM and LCM and it is discussed the difference between MCM and LCM and it is discussed the difference between		THE WITNESS: No.	2	A. Yes, they do.	
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6 A. No. 7 MS. SUTHERLAND: Objection. 8 BY MR. GOSS: 9 Q. Let's talk a little bit about the 17 TVT-O. And you talked a little bit this 18 morning with defense counsel about Prolene 19 mesh, and there was some discussion about 11 morning with defense counsel about Prolene 11 morning with defense counsel about Prolene 12 mesh, and there was some discussion about 13 fraying. 14 Do you recall that? 15 A. Yes, I do. 16 Q. In your investigations of in 17 your investigation of Ethicon's files, did 18 you uncover any documents that discussed any 19 complaints about the Prolene mesh product 19 fraying? 21 A. Yes, I did. 22 Q. Did you uncover any documents that 24 discussed particle loss with respect to 25 A. Yes. 26 A. Yes. 27 A. Yes, I did. 28 Yes. 29 Page 407 20 Lid you uncover any documents that 20 discussed particle loss with respect to 21 Q. Did you review any documents that 22 discussed the difference between MCM and LCM 23 with respect to fraying and particle loss? 24 A. Yes, I did. 25 Q. Did you review any documents that 26 discussed the difference between MCM and LCM 37 A. Yes, I did. 38 YMR. GOSS: 39 Unard remaining particles that had been lost from the mesh in the box. 39 MR. GOSS: 40 Prolene mesh? 41 Q. Did you uncover any documents that 42 discussed particle loss with respect to 43 Prolene mesh? 44 A. Yes, I did. 55 Q. Did you review any documents that 56 Q. I'm going to hand you what's been 57 marked for identification.) 58 PMR. GOSS: 59 Q. I believe it's a women's division 59 wour opinions that you're giving today? 60 A. Yes, the M. Holloway for the Gynecare a laking. 71 (Exhibit Number 26 was 72 M. Yes, the did the tape became particles, and after 73 marked for identification.) 74 MS. SUTHERLAND: Objection. 75 Page 407 76 MR. GOSS: 77 A. Yes, I did. 78 MR. GOSS: 79 MR. GOSS: 79 A. Yes, I tis. 79 WR. GOSS: 70 A. Yes, I tis. 70 Page 407 71 MR. SUTHERLAND: Objection. 71 MR. SUTHERLAND:		=	5	, , , , , , , , , , , , , , , , , , , ,	
8 BY MR. GOSS: 9 Q. Let's talk a little bit about the 10 TVT-O. And you talked a little bit this 11 morning with defense counsel about 4 a customer's experience 12 mesh, and there was some discussion about 13 fraying. 14 Do you recall that? 15 A. Yes, I do. 16 Q. In your investigation of Ethicon's files, did 17 your investigation of Ethicon's files, did 18 you uncover any documents that discussed any 19 complaints about the Prolene mesh product 20 fraying? 21 A. Yes, I did. 22 Q. Did you uncover any documents that 23 discussed particle loss with respect to 24 Prolene mesh? 25 A. Yes, I did. 26 Q. Did you review any documents that 27 discussed the difference between MCh and LCM 28 Q. Did you review any documents that 29 discussed the difference between MCh and LCM 30 vith respect to fraying and particle loss? 4 A. Yes, I did. 5 Q. Did you review any documents that 2 discussed the difference between MCh and LCM 3 vith respect to fraying and particle loss? 4 A. Yes, I did. 5 Q. Did you review any documents that 5 Q. Did those documents form a basis of 6 your opinions that you're giving today? 7 A. Yes, they did. 9 Q. Tim going to hand you what's been 9 marked as Pence Exhibit 26. 10 /// 11 (Exhibit Number 26 was marked for identification.) 11 (Exhibit Number 26 was marked for identification.) 12 Prolene mesh construction." 13 document about reviewed from Ethicon's files? 14 (Exhibit Number 26 was marked for identification.) 15 MS MR. GOSS: 16 MS. SUTHERLAND: Objection. 17 What does that mean, "Fraying is inherent in the product" inherent in the product" 19 MS MR. GOSS: 10 MS SUTHERLAND: Objection. 11 (Exhibit Number 26 was marked for identification.) 12 (Exhibit Number 26 was marked for identification.) 13 BY MR. GOSS: 14 A. Yes, it is. 15 MS. SUTHERLAND: Objection. 16 MS MS MS. SUTHERLAND: Objection. 17 MS. SUTHERLAND: Objection. 18 With respect to fraying and particle loss even without stretching but when the product" when the product" in the produc					
8 BY MR. GOSS: Q. Let's talk a little bit about the 10 TVT-O. And you talked a little bit this 11 morning with defense counsel about Prolene 12 mesh, and there was some discussion about 13 fraying. 14 Do you recall that? 15 A. Yes, I do. 16 Q. In your investigations of — in 17 your investigation of Ethicon's files, did 18 you uncover any documents that discussed any 19 complaints about the Prolene mesh product 20 fraying? 21 A. Yes, I did. 22 Q. Did you uncover any documents that 23 discussed particle loss with respect to 24 Prolene mesh? 25 A. Yes. 26 Did you review any documents that 27 discussed the difference between MCM and LCM 28 with respect to fraying and particle loss? 4 A. Yes, I did. 5 Q. Did those documents form a basis of 6 your opinions that you're giving today? 7 A. Yes, they did. 8 Q. I'm going to hand you what's been 9 marked as Pence Exhibit 26. 9 marked for identification.) 10 /// 11 (Exhibit Number 26 was marked for identification.) 11 (Exhibit Number 26 was marked for identification.) 12 make for identification.) 13 with respect to fraying and particle loss? 14 A. Yes, it is. 15 A. Yes, it is. 16 Q. And is this a document relating to 17 Traying is inherent in the product based by Ethicon is a degradation of the reverse and the tape became particles, and after implantation of the TVT device, the staff found remaining particles that had been lost from the mesh in the box. 16 BY MR. GOSS: 17 Q. And Carol — this is a letter from Carol Holloway. She is a product complaint analyst worldwide customer quality for Gynecare. 18 JW MR. GOSS: 20 A. Yes. 21 Is Gynecare a part of J&J and Ethicon? 22 A. Yes. 23 MS. SUTHERLAND: Objection. 24 Prolene mesh? 25 A. That's correct. 24 Q. And one of the sentences — explain to the jury this sentence: "Fraying is inherent in the product" — this is inherent in the product based upon the mesh construction." 3 With respect to fraying and particle loss? 4 A. Yes, it is. 5 Q. Is that a todument relating to a TVT device? 18 A. Yes, it is. 19 Q. What's the date of this d					
9 Q. Let's talk a little bit about the 10 TVT-O. And you talked a little bit this 11 morning with defense counsel about Prolene 12 mesh, and there was some discussion about 13 fraying. 14 Do you recall that? 15 A. Yes, 1 do. 16 Q. In your investigations of in 17 your investigation of Ethicon's files, did 18 you uncover any documents that discussed any 19 complaints about the Prolene mesh product 20 fraying? 21 A. Yes, I did. 22 Q. Did you uncover any documents that 23 discussed particle loss with respect to 24 Prolene mesh? 25 A. Yes. 26 Did you review any documents that 27 discussed the difference between MCM and LCM 28 with respect to fraying and particle loss? 29 A. Yes, I did. 20 Q. Did you review any documents that 21 discussed the difference between MCM and LCM 22 discussed the difference between MCM and LCM 23 with respect to fraying and particle loss? 24 A. Yes, I did. 25 Q. Did you review any documents that 26 discussed the difference between MCM and LCM 27 A. Yes, This. 28 Q. I' believe it's a women's division  Page 407 29 Q. Did you review any documents that 20 discussed the difference between MCM and LCM 21 discussed the difference between MCM and LCM 22 discussed the difference between MCM and LCM 23 with respect to fraying and particle loss? 29 Q. Did you review any documents form a basis of of your opinions that you're giving today? 30 Q. Tim going to hand you what's been marked as Pence Exhibit 26. 31 promption that you're giving today? 42 Q. Is that a document that you 43 BY MR. GOSS: 44 Q. I'm going to hand you what's been marked for identification.) 45 Prolene mesh construction." 46 What does that mean, "Fraying is inherent in the product" with the mechanical cutting, what occurs is that there is the term that has been used by Ethicon is a degradation of the mesh structure so that the structure so that the structure particularly when they there's par					
10 TVT-O. And you talked a little bit this morning with defense counsel about Prolene 11 morning with defense counsel about Prolene 12 mesh, and there was some discussion about 13 fraying. 14 Do you recall that? 15 A. Yes, I do. 16 Q. In your investigation of Ethicon's files, did 17 your investigation of Ethicon's files, did 18 you uncover any documents that discussed any 19 complaints about the Prolene mesh product 19 fraying? 20 A. Yes, I did. 21 Q. Did you uncover any documents that 22 discussed particle loss with respect to 23 Prolene mesh? 24 Prolene mesh? 25 A. Yes. 26 Q. Did you review any documents that 27 discussed the difference between MCM and LCM 28 with respect to fraying and particle loss? 29 A. Yes, I did. 30 Q. Did you review any documents that 31 discussed the difference between MCM and LCM 32 with respect to fraying and particle loss? 4 A. Yes, I did. 5 Q. Did you review any documents that 4 discussed the difference between MCM and LCM 34 with respect to fraying and particle loss? 4 A. Yes, I did. 5 Q. Did you review any documents form a basis of 4 your opinions that you're giving today? 5 A. Yes, the yid. 6 Q. I'm going to hand you what's been 9 marked as Pence Exhibit 26. 9 marked for identification.) 10 /// 11 (Exhibit Number 26 was 11 metape became particles, and after 12 implantation of the TVT device, the 13 staff found remaining particles that had 14 been lost from the mesh in the box. 16 D. A. Yes, I did. 17 Carol Holloway. She is a product complaint analyst worldwide customer quality for 18 Graying. 18 MR. GOSS: 20 Is Gynecare. 21 A. Yes, I did. 22 A. Yes, I did. 33 Staff found remaining particles that had 44 been lost from the mesh in the box. 24 D. And Carol this is a letter from 25 A. Yes, I did. 26 A. Yes, I did. 27 A. Yes, I did. 28 Q. Did you uncover any documents that 29 discussed the difference between MCM and LCM 30 with respect to fraying and particle some analyst worldwide customer quality for 31 Granl Holloway. She is a product complaint analyst worldwide customer quali					
11 morning with defense counsel about Prolene 12 mesh, and there was some discussion about 13 fraying. 14 Do you recall that? 15 A. Yes, I do. 16 Q. In your investigations of — in 17 your investigation of Ethicon's files, did 18 you uncover any documents that discussed any 19 complaints about the Prolene mesh product 20 fraying? 21 A. Yes, I did. 22 Q. Did you uncover any documents that 23 discussed particle loss with respect to 24 Prolene mesh? 25 A. Yes. 26 Q. Did you review any documents that 27 discussed the difference between MCM and LCM 28 With respect to fraying and particle loss? 3 A. Yes, I did. 4 A. Yes, I did. 5 Q. Did you review any documents that 2 discussed the difference between MCM and LCM 3 with respect to fraying and particle loss? 4 A. Yes, I did. 5 Q. Did those documents form a basis of 6 your opinions that you're giving today? 7 A. Yes, they did. 8 Q. I'm going to hand you what's been 9 marked as Pence Exhibit 26. 9 marked for identification.) 11 (Exhibit Number 26 was 12 marked for identification.) 12 marked for identification.) 13 BY MR. GOSS: 14 A. Yes, it is. 15 Limplantation of the TVT device; the 16 implantation of the TVT device, the 17 implantation of the TVT device, the 18 staff found remaining particles that had 14 been lost from the mesh in the box. 16 MR GOSS: 17 Q. And Carol — this is a letter from 18 YMR. GOSS: 18 Gynecare a part of J&J and 21 Ethicon? 22 M. Yes. 23 MS. SUTHERLAND: Objection. 24 BY MR. GOSS: 25 Q. I believe it's a women's division 25 A. That's correct. 3 Q. And one of the sentences — explain 4 to the jury this sentence: "Fraying is 5 inherent in the product" — this is 6 MS. Holloway for the Gynecare talking. 7 "Fraying is inherent in the product based 16 upon the mesh construction." 17 What does that mean, "Fraying is 18 inherent in the product." — this is 19 what does that mean, "Fraying is 10 inherent in the product is designed and with the 11 the tape location of the mesh structure is a tructure so that the structure 18 particle loss even without stretching		=			
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13 fraying. 14 Do you recall that? 15 A. Yes, I do. 16 Q. In your investigations of in 17 your investigation of Ethicon's files, did 18 you uncover any documents that discussed any 19 complaints about the Prolene mesh product 20 fraying? 21 A. Yes, I did. 22 Q. Did you uncover any documents that 23 discussed particle loss with respect to 24 Prolene mesh? 25 A. Yes. 26 Q. Did you review any documents that 27 discussed the difference between MCM and LCM 28 with respect to fraying and particle loss? 29 A. Yes, I did. 20 Did you review any documents that 21 discussed the difference between MCM and LCM 22 discussed the difference between MCM and LCM 23 discussed the difference between MCM and LCM 24 discussed the difference between MCM and LCM 25 discussed the difference between MCM and LCM 26 with respect to fraying and particle loss? 27 A. Yes, I did. 28 Q. Did you review any documents form a basis of o your opinions that you're giving today? 29 A. Yes, they did. 30 Q. Did you review any documents form a basis of your opinions that you're giving today? 31 A. Yes, they did. 41 been lost from the mesh in the box. 42 BY MR. GOSS: 42 Q. And Carol this is a letter from 43 Carol Holloway. She is a product complaint analyst worldwide customer quality for 45 Gynecare. 46 Ethicon? 47 A. Yes. 48 Pyes. 49 A. Yes. 40 SUTHERLAND: Objection. 40 Prolene mesh 40 Prolene mesh 51 Or something? 52 A. That's correct. 53 Ond one of the sentences explain to the jury this sentence: "Fraying is inherent in the product" this is 6 Ms. Holloway for the opinions that you're giving today? 51 Or something? 52 A. That's correct. 53 MS. SUTHERLAND: Objection. 54 A. Yes, I did. 55 Q. Did those documents form a basis of 5 inherent in the product" this is 6 Ms. Holloway for the opinions that you're giving today? 55 Inherent in the product" this is 6 Ms. Holloway for the opinions that the product opinions that the product opinions that the product opinions that the product opinions the mesh construction. 56 Ms. Holloway for the opi					
14 been lost from the mesh in the box.  15 BY MR. GOSS: 16 Q. In your investigations of in 17 your investigation of Ethicon's files, did 18 you uncover any documents that discussed any 19 complaints about the Prolene mesh product 20 fraying? 21 A. Yes, I did. 22 Q. Did you uncover any documents that 23 discussed particle loss with respect to 24 Prolene mesh? 25 A. Yes. 26 Prolene mesh? 27 A. Yes, I did. 28 discussed the difference between MCM and LCM 39 with respect to fraying and particle loss? 4 A. Yes, I did. 5 Q. Did you review any documents that 2 discussed the difference between MCM and LCM 3 with respect to fraying and particle loss? 4 A. Yes, I did. 5 Q. Did you review any documents that 6 discussed the difference between MCM and LCM 7 with respect to fraying and particle loss? 8 Q. I believe it's a women's division  Page 407 2 A. That's correct. 3 Q. And one of the sentences explain to the jury this sentence: "Fraying is inherent in the product" this is inherent in the product" this is inherent in the product" this is inherent in the product based upon the mesh construction." 9 marked as Pence Exhibit 26. 10 /// 11 (Exhibit Number 26 was marked for identification.) 12 marked for identification.) 13 BY MR. GOSS: 24 BY MR. GOSS: 25 Q. I believe it's a women's division  Page 407 2 A. That's correct. 3 Q. And one of the sentences explain to the jury this sentence: "Fraying is inherent in the product" this is inherent in the product" this is inherent in the product." this		•		·	
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22 Q. Did you uncover any documents that discussed particle loss with respect to Prolene mesh? 25 A. Yes.  26 Prolene mesh? 27 Prolene mesh? 28 Prolene mesh? 29 Prolene mesh? 29 Prolene mesh? 20 Page 407 21 Q. Did you review any documents that discussed the difference between MCM and LCM 20 With respect to fraying and particle loss? 21 A. That's correct. 22 A. That's correct. 23 Q. And one of the sentences explain to the jury this sentence: "Fraying is inherent in the product" this is your opinions that you're giving today? 23 MS. SUTHERLAND: Objection. 24 BY MR. GOSS: 25 Q. I believe it's a women's division  Page 407 2 A. That's correct. 3 Q. And one of the sentences explain to the jury this sentence: "Fraying is inherent in the product" this is 4 to the jury this sentence: "Fraying is inherent in the product" this is 4 to the jury this sentence: "Fraying is inherent in the product based 4 upon the mesh construction." 26 Ms. Holloway for the Gynecare talking. 27 "Fraying is inherent in the product based 4 upon the mesh construction." 28 What does that mean, "Fraying is inherent in the product." 29 What does that mean, "Fraying is inherent in the product." 30 Inherent in the product." 31 MS. SUTHERLAND: Objection. 4 THE WITNESS: The way the 4 mechanical cutting, what occurs is that 4 there is the term that has been used 5 by Ethicon is a degradation of the mesh 5 tructure so that the structure 5 that 4 there is the term that has been used 5 by Ethicon is a degradation of the mesh 5 tructure so that the structure 6 when particularly when they there's 5 particularly when they there's 6 particularly when the 7 porduct is stretched, that the structure 6 but when particularly when the 9 product is stretched, that the structure 6 but when particularly when the 9 product is stretched, that the structure 6 but when particularly when the 9 product is stretched.		fraying?			
23 discussed particle loss with respect to 24 Prolene mesh? 25 A. Yes.  28 Page 407  1 Q. Did you review any documents that 2 discussed the difference between MCM and LCM 3 with respect to fraying and particle loss? 4 A. Yes, I did. Q. Did those documents form a basis of 6 your opinions that you're giving today? 7 A. Yes, they did. 8 Q. I'm going to hand you what's been 9 marked as Pence Exhibit 26. 10 (Exhibit Number 26 was 11 (Exhibit Number 26 was 12 marked for identification.) 13 BY MR. GOSS: Q. I believe it's a women's division  Page 407  1 or something? 2 A. That's correct. 3 Q. And one of the sentences explain to the jury this sentence: "Fraying is inherent in the product" this is 6 Ms. Holloway for the Gynecare talking. 7 "Fraying is inherent in the product based upon the mesh construction." 9 What does that mean, "Fraying is inherent in the product"? 11 (Exhibit Number 26 was 11 MS. SUTHERLAND: Objection. 12 THE WITNESS: The way the product is designed and with the 14 Q. Is that a document that you 15 reviewed from Ethicon's files? 16 A. Yes, it is. 17 Q. And is this a document relating to a TVT device? 18 A. Yes, it is. 19 particle loss even without stretching 20 What's the date of this document? 21 A. That's correct. 22 A. That's correct. 3 Q. And one of the sentences explain to the jury this sentence: "Fraying is inherent in the product" this is 4 to the jury this sentence: "Fraying is inherent in the product" this is 5 (Ms. Holloway for the Gynecare talking. 7 "Fraying is inherent in the product" the term that has been used by Ethicon is a degradation of the mesh structure particularly when they there's 19 particle loss even without stretching 20 Uhat's the date of this document? 21 A. That's correct. 3 Q. I'm going to hand you what's been 4 to the jury this sentence: "Fraying is inherent in the product" the term that has been used by Ethicon is a degradation of the mesh structure particularly when they there's 19 particle loss even without stretching 20 Uhat's the date o	21	A. Yes, I did.	21	Ethicon?	
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25 A. Yes.  Page 407  Q. Did you review any documents that discussed the difference between MCM and LCM discussed the difference between MCM and LCM 2 A. That's correct.  With respect to fraying and particle loss? 3 Q. And one of the sentences explain 4 to the jury this sentence: "Fraying is inherent in the product" this is 5 your opinions that you're giving today? 6 Ms. Holloway for the Gynecare talking. 7 "Fraying is inherent in the product based 8 Q. I'm going to hand you what's been 9 marked as Pence Exhibit 26. 9 What does that mean, "Fraying is inherent in the product"?    Manual Company of the Gynecare talking. 7 "Fraying is inherent in the product based 8 upon the mesh construction." 9 What does that mean, "Fraying is inherent in the product"? 10 inherent in the product"? 11 MS. SUTHERLAND: Objection. 12 THE WITNESS: The way the 13 BY MR. GOSS: 13 product is designed and with the 14 Q. Is that a document that you 14 mechanical cutting, what occurs is that 15 reviewed from Ethicon's files? 15 there is the term that has been used 16 A. Yes, it is. 16 by Ethicon is a degradation of the mesh 17 structure so that the structure 18 a TVT device? 18 particularly when the 29 particle loss even without stretching 20 but when particularly when the 21 product is stretched, that the structure	23	discussed particle loss with respect to	23	MS. SUTHERLAND: Objection.	
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21 A. October 12, 2005. 21 product is stretched, that the structure		·			
1 ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' ' '		•			
177 O AND WOO IS CARD HOUNWAY?	22	Q. And who is Carol Holloway?	22	along the edges of the mesh is lost, and	
23 A. She's a product complaint analyst 23 the product can rope and curl and		- ,			
24 in worldwide customer quality. 24 particles fall off.		·			
25 Q. By the way, when we talk about TVT 25 BY MR. GOSS:		·		•	
25 S. 57 S. 5 Hajj Mich He Will about 171	125	(). By the way, when we talk about IVI	ノち	BY MR. (7055:	ı

		Page 410			Page 412
1	Q. Under the re line there, it has a		1	approximately 36 years. Engineering fellow	
2	lot number. Can you tell from that lot		2	at this point, I believe.	
3	number whether this lot whether this		3	Q. So, and he's writing to Janice	
4	product that's being discussed in this		4	Burns. I believe she's with @ethgb means	
5	exhibit is mechanical cut?		5	Ethicon Great Britain; is that right?	
6	A. Yes.		6	A. Yes, that's my understanding.	
7	Q. And what is it?		7	Q. And, again, with these emails, we	
8	A. It's mechanically cut.		8	start from the back, which should be the	
9	Q. And how do you know that?		9	second page; right?	
10	A. There's no L for laser cut as well		10	A. Yes.	
11	as in October, 2005, the laser cut was not		11	Q. And that appears to be, on the	
12	yet available.		12	second page, an email from Bernhard Fischer,	,
13	Q. So what should a reasonable,		13	who appears to be from marketing Gynecare	
14	prudent manufacturer do when it receives a		14	and Breast Care in Vienna.	
15	letter like this?		15	A. Correct.	
16	MS. SUTHERLAND: Objection.		16	Q. And he is writing Janice Burns in	
17	THE WITNESS: There's a number		17	Great Britain regarding TVT complaints; is	
18	of different things it should do. It		18	that right?	
19	should do further investigation. It		19	A. Yes.	
20	should open up corrective and preventive		20	Q. And is this email something that	
21	action, determine what the cause of this		21	you relied upon in forming your opinions?	
22	is, and then look at what it can do to		22	A. Yes, it is.	
23	mitigate risks.		23	Q. And is this time period a time	
24	And it should investigate, like		24	period before there was laser-cut mesh?	
25	this loss of particles and the		25	A. Yes, it is.	
		Page 411			Page 413
		rage +11			rage 413
1	stretching that occurs, whether or	rage 411	1	Q. So the mesh we're talking about	rage 413
2	not how that I should say how that	rage 411	2	here would be mechanically cut mesh?	rage +13
2	not how that I should say how that impacts the safety and effectiveness of	rage 411	2	here would be mechanically cut mesh?  A. Yes.	rage +15
2 3 4	not how that I should say how that impacts the safety and effectiveness of the tape when implanted.	rage 411	2 3 4	here would be mechanically cut mesh? A. Yes. Q. Okay. And what's Janice Burns	rage +13
2 3 4 5	not how that I should say how that impacts the safety and effectiveness of the tape when implanted. BY MR. GOSS:	rage 411	2 3 4 5	here would be mechanically cut mesh? A. Yes. Q. Okay. And what's Janice Burns what is Bernhard Fischer explaining to	rage +13
2 3 4 5 6	not how that I should say how that impacts the safety and effectiveness of the tape when implanted. BY MR. GOSS: Q. Let me hand you what's been marked	rage +II	2 3 4 5 6	here would be mechanically cut mesh? A. Yes. Q. Okay. And what's Janice Burns what is Bernhard Fischer explaining to Janice Burns in this email?	rage +13
2 3 4 5 6 7	not how that I should say how that impacts the safety and effectiveness of the tape when implanted.  BY MR. GOSS:  Q. Let me hand you what's been marked as Exhibit 27 to your deposition.	rage HII	2 3 4 5 6 7	here would be mechanically cut mesh? A. Yes. Q. Okay. And what's Janice Burns what is Bernhard Fischer explaining to Janice Burns in this email? MS. SUTHERLAND: Objection.	rage 413
2 3 4 5 6 7 8	not how that I should say how that impacts the safety and effectiveness of the tape when implanted.  BY MR. GOSS:  Q. Let me hand you what's been marked as Exhibit 27 to your deposition.  (Exhibit Number 27 was	rage +11	2 3 4 5 6 7 8	here would be mechanically cut mesh?  A. Yes. Q. Okay. And what's Janice Burns what is Bernhard Fischer explaining to Janice Burns in this email?  MS. SUTHERLAND: Objection. THE WITNESS: It's about two	rage 413
2 3 4 5 6 7 8	not how that I should say how that impacts the safety and effectiveness of the tape when implanted.  BY MR. GOSS: Q. Let me hand you what's been marked as Exhibit 27 to your deposition.  (Exhibit Number 27 was marked for identification.)	rage +11	2 3 4 5 6 7 8 9	here would be mechanically cut mesh?  A. Yes. Q. Okay. And what's Janice Burns what is Bernhard Fischer explaining to Janice Burns in this email?  MS. SUTHERLAND: Objection. THE WITNESS: It's about two TVT complaints, both dealing with the	rage 413
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		Page 414			Page 416
1	and was exactly the original issue that		1	Should a manufacturer ever manufacture a	
2	stopped TVT blue for months. The fix, I'm		2	product so that a defect could not be	
3	not sure how complete, is to cut the mesh		3	apparent to the user?	
4	using ultrasonics, but it has not been		4	MS. SUTHERLAND: Objection.	
5	validated. I'm not sure where it sits on		5	THE WITNESS: No.	
6	the operations priority list."		6	BY MR. GOSS:	
7	What does that mean?		7	Q. Would that be a violation of	
8	MS. SUTHERLAND: Objection.		8	standards in the industry?	
9	THE WITNESS: It means that the		9	MS. SUTHERLAND: Objection.	
10	company has identified a way to fix the		10	THE WITNESS: Absolutely.	
11	fraying, but they've not implemented it.		11	BY MR. GOSS:	
12	BY MR. GOSS:		12	Q. I'm handing you what's been marked	
13	Q. Okay. In the company documents, do		13	as Exhibit 28.	
14	they sometimes use ultrasonic and LCM		14	(Exhibit Number 28 was	
15	interchangeably?		15	marked for identification.)	
16	A. They're different, but they've used		16	BY MR. GOSS:	
17	ultrasonic cutting to test material that		17	Q. Is that a document that you	
18	they that they've where they've later		18	reviewed from Ethicon's files?	
19	marketed laser-cut mesh. They've done the		19	A. Yes, it is.	
20	testing with ultrasonically cut mesh.		20	Q. Is this a document that you relied	
21	Q. Okay. So go down to the third I		21	upon in forming your opinions that you're	
22	guess the fourth paragraph there. "This is		22	giving today?	
23	not going away any time soon, and		23	A. Yes, it is.	
24	competition will have a field day. Major		24	Q. And this is another one of those	
25	damage control offensive needs to start to		25	two-page emails. It appears to be it	
25	damage control offensive fields to start to		23	two page emails. It appears to be	
		Page 415			Page 417
1	educate the rens and the surgeons unfront	Page 415	1	appears to involve at the bottom. Dan	Page 417
1 2	educate the reps and the surgeons upfront	Page 415	1 2	appears to involve, at the bottom, Dan Smith, who we just talked about: right?	Page 417
2	that they will see blue shit, and it is	Page 415	2	Smith, who we just talked about; right?	Page 417
2	that they will see blue shit, and it is okay. This is why I wanted to launch TVT-O	Page 415	2 3	Smith, who we just talked about; right? A. Yes.	Page 417
2 3 4	that they will see blue shit, and it is okay. This is why I wanted to launch TVT-O in clear."	Page 415	2 3 4	Smith, who we just talked about; right? A. Yes. Q. Janice Burns, who we just talked	Page 417
2 3 4 5	that they will see blue shit, and it is okay. This is why I wanted to launch TVT-O in clear."  Is there anything in that sentence	Page 415	2 3 4 5	Smith, who we just talked about; right? A. Yes. Q. Janice Burns, who we just talked about as well?	Page 417
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2 3 4 5 6 7	that they will see blue shit, and it is okay. This is why I wanted to launch TVT-O in clear."  Is there anything in that sentence that's important to your opinions?  MS. SUTHERLAND: Objection.	Page 415	2 3 4 5 6 7	Smith, who we just talked about; right? A. Yes. Q. Janice Burns, who we just talked about as well? A. Yes. Q. Charlotte Owens, who appears to be	Page 417
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1	Do you see that?	1	MS. SUTHERLAND: Objection.	-
2	A. I do.	2	THE WITNESS: They're the	
3	Q. And I want to focus on the third	3	international globally accepted standard	
4	sentence there, the third element there. It	4	of care, yes.	
5	says, "Reassure your doctors" and, by the	5	BY MR. GOSS:	
6	way, Steve Bell is director of marketing;	6	Q. Okay. Is there any debate about	
7		7	that?	
8	right?	8		
	A. Yes, for Europe.		MS. SUTHERLAND: Objection. THE WITNESS: No.	
9	Q. And he's saying, "Reassure your	9		
10	doctors that this is part of the success of	10	///	
11	TVT. The way we have cut the mesh makes the	11	BY MR. GOSS:	
12	edges softer, and we feel that this has been	12	Q. Okay. Let me under "Why is	
13	a crucial success factor in TVT. Reassure	13	Clinical Evaluation Important," it says, the	
14	them that Prolene has proven to be inert,	14	last sentence of the first paragraph there,	
15	and there are hundreds of papers going back	15	"That any claims made about the device's	
16	25 years to reinforce this point. These	16	performance and safety should be supported	
17	particles will not cause any problem."	17	by suitable evidence."	
18	What I want to focus on is the	18	Do you see that?	
19	statement "Reassure them that Prolene has	19	A. Yes.	
20	proven to be inert, and there are hundreds	20	Q. The statement that Steve bell is	
21	of papers going back 25 years to reinforce	21	telling his marketing people to say to	
22	this point."	22	doctors, does that violate that provision of	
23	Is that statement you've	23	the Global Harmonization Task Force?	
24	reviewed the literature in that regard, have	24	MS. SUTHERLAND: Objection.	
25	you not?	25	THE WITNESS: It certainly	
	you not.	23	THE WITHESS: It certainly	
1	Page 419			Page 421
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		Page 422		Pa	nge 424
1	and testimony that says this is a product		1	string involving, among others, David	
2	defect, and the company is aware it's		2	Menneret who is a complaint investigator and	
3	ongoing but yet has not addressed it.		3	regulatory contact for Ethicon; is that	ı
4	Q. As of the 2004 time period here,		4	right?	
5	the time period of these emails, have you		5	A. That's correct.	
6	seen anything in Ethicon's files where it's		6	Q. It also involves if you look at	
7	done a clinical test on particle loss?		7	the front page, Dan Smith is involved.	ı
8	A. No. None.		8	Does this look like the TVT people?	ı
9	Q. And whether or not it's safe?		9	A. Yes.	ı
10	MS. SUTHERLAND: Objection.		10	Q. Okay. And the first document,	ı
11	THE WITNESS: That's correct.		11	Exhibit 29, essentially encloses the	
12	No testing.		12	exhibit the letter that's marked as	
13	BY MR. GOSS:		13	Exhibit 30; is that right?	ı
14			14	•	
	Q. Okay. Would a reasonable, prudent			A. I'm sorry. Could you reask that?	
15	manufacturer at this time have begun		15	Q. The first document, Exhibit 29, is	
	clinical testing, at least by this time, to		16	really enclosing and transferring the letter	
17	determine whether or not this particle loss		17	marked as Exhibit 30; right?	ı
	was an issue?		18	A. Yes, that's correct.	
19	A. If they were going to maintain this		19	Q. And what is Exhibit 30?	
20	on the market, absolutely.		20	A. Exhibit 30 is a letter from a Dr.	
21	THE VIDEOGRAPHER: Can we go		21	Eberhard who has been a major user, actually	
22	off for 10 seconds?		22	an important customer in Switzerland,	
23	MR. GOSS: Sure.		23	important user of Ethicon's products mesh	
24	THE VIDEOGRAPHER: With the		24	products.	
25	approval of counsel, I'm going off the		25	Q. I believe on the second page of	
		Page 423		Pa	nge 425
1	record. The time is approximately	1 age 123	1	Exhibit 29, they describe him as an opinion	.gc .23
2	7:08 p.m.		2	leader?	
3	(Recess taken from		3	A. Yes.	
4	7:08 p.m. to 7:10 p.m.)		4	Q. It says, on Exhibit 29, "He knows	
5	THE VIDEOGRAPHER: With the		5	everything about tape, and if we lost him,	
6	approval of counsel, back on the record.		6	we lost all."	
7	The time is approximately 7:10 p.m.		7	Do you see that?	
8	BY MR. GOSS:		8	A. Yes.	
9	Q. I'm going to hand you two documents		9	Q. By the way, what's an opinion	
10	that I believe go together marked as		10	leader?	
11	Exhibits 29 and 30.		11	A. An opinion leader is, in this case,	
12	(Exhibit Numbers 29 and 30		12	a doctor who is very well recognized in his	
13	were marked for identification.)		13	field of practice as an authority.	
14	BY MR. GOSS:		14	Q. Okay. And so this opinion leader	
15	Q. Have you seen those documents		15	who they describe in the email as someone	
16	before?		16	who knows everything about tape and if we	
17	A. Yes, I certainly have.		17	lost him, we lost all, and his letter on	
18	Q. Are those documents that came out		18	Exhibit 30, he states, "Dear Emilie, Please	
19	of Ethicon's files?		19	find attached a TVT tape which was used as a	
20	A. Yes.		20	demo unit for patients before they have	
21	Q. Are these documents that you		21	their operation.	
22	reviewed and relied upon in forming your		22	"Already at the operation, it is	
23	opinions?		23	embarrassing to see how the tape is	
24	A. Yes, they are.		24	crumbling, but it gets worse if there is a	
141	· · · · · · · · · · · · · · · · · · ·				
25	Q. And this appears to be an email		25	stretch on the tape. It is urgent that	

		1		
		Page 426		Page 42
1	Johnson & Johnson quickly produce a tape	5	1	violation of the standards in the industry
2	that is solid and weaved. If not, I have		2	as set forth in the documents that we've
3	the convenience that the doctors will change		3	looked at?
4	the tape and will get others. I can't		4	MS. SUTHERLAND: Objection.
5	understand that no one will solve that		5	
				THE WITNESS: Yes, it is.
6	problem for such a long time.		6	BY MS. SUTHERLAND:
7	"At the latest, as the tape has		7	Q. You talked earlier today about a
8	become blue, everyone has realized the		8	some slides or a PowerPoint that Gene
9	quality of the tape is terrible." Then he		9	Kammerer did.
10	attaches some pictures. And it says the		10	Do you recall that?
11	tape needs to be weaved; so it doesn't		11	A. Yes, I do.
12	crumble.		12	Q. Where he had done some comparisons
13	Why is a document like this why		13	of mechanically cut mesh and laser-cut mesh?
14	do you find something like this, if you do,		14	A. Yes.
15	important in their files?		15	Q. I'm going to hand you what's been
16	MS. SUTHERLAND: Object to the		16	marked as Exhibits 31 and 32 and ask you if
17	reading of the document.		17	those were the slides that you were talking
18	THE WITNESS: It's critically		18	about.
19	important. It's another complaint. The		19	(Exhibit Numbers 31 and 32
20	company has gotten now multiple		20	were marked for identification.)
21	complaints about the fraying of its		21	THE WITNESS: Yes, they are.
22	product from the doctors who are using		22	BY MR. GOSS:
23	it. And companies have a responsibility		23	Q. And were those slides did you
24	to investigate complaints, to implement		24	find those were those in Ethicon's files?
25	corrective and preventive actions as		25	A. Yes.
23	corrective and preventive actions as		3	71. 1651
		Page 427		Page 42
1		Page 427	1	Page 42
1 2	appropriate to change the issue, to	Page 427	1	Q. And was there an email accompanying
2	appropriate to change the issue, to address the issue, I mean to say, and	Page 427	2	Q. And was there an email accompanying this that demonstrated that they were done
2 3	appropriate to change the issue, to address the issue, I mean to say, and correct it and study if it's causing	Page 427	2 3	Q. And was there an email accompanying this that demonstrated that they were done by Gene Kammerer?
2 3 4	appropriate to change the issue, to address the issue, I mean to say, and correct it and study if it's causing safety and efficacy risks.	Page 427	2 3 4	Q. And was there an email accompanying this that demonstrated that they were done by Gene Kammerer?  A. Yes.
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Page 430 Page 432 1 Q. And he's sending these to a number 1 it ropes, and it can rope underneath -- you 2 of Ethicon people; is that right? know, the idea of the sling, the tape is that it fits under the urethra to support 3 A. Yes, he is. 3 4 Q. Now, prior to August 28 of 2006, 4 the urethra to prevent stress urinary 5 did you uncover any documents in your 5 incontinence, and that roping can affect investigation where something like this 6 effectiveness as well as safety. 6 7 comparison had been done prior to 2006? 7 Q. And what does he conclude with 8 MS. SUTHERLAND: Objection. 8 respect to mechanically cut mesh versus 9 THE WITNESS: No. I don't 9 laser-cut mesh as to roping? 10 recall having seen anything earlier than 10 A. That the mechanically cut mesh 11 this of this type of comparison. 11 ropes, and the roping does not occur with 12 BY MR. GOSS: 12 the laser-cut mesh. 13 Q. Okay. So and what is -- now let's 13 O. And what did he -- what did he move to the slides. conclude about particle loss with respect to 14 14 mechanically cut mesh versus laser-cut mesh? 15 A. Okay. 15 A. There's significant particle loss 16 Q. Okay. What is it that he's doing 16 in Exhibits 31 and 32, just generally? with the mechanically cut mesh where, by 17 17 18 A. He's taken pictures of laser-cut 18 contrast, the laser-cut mesh, there's either mesh versus mechanically cut mesh, no particle lost or almost no particles 19 19 20 particularly on stretching. 20 lost. Q. Okay. Let's look at Exhibit 31. 21 Q. And let's go to the third page of 21 22 That's the first one; right? 22 that first exhibit where it's a side-by-side 23 A. Yes. 23 Q. And does he describe his results 24 24 Do you see that? A. Yes, I do. 25 25 there? Page 431 Page 433 A. Yes, he does. 1 Q. And tell me what's going on here. 1 2 2 Q. And generally, what is he saying A. This is a picture that shows what 3 about the results of this comparison that 3 he described. It's a picture of the he's done, this engineering fellow has done mechanically cut mesh that's been relaxed 4 4 5 who works for Ethicon? 5 after it's been pulled 50 percent 6 6 elongation, and the same pictures of the MS. SUTHERLAND: Objection. 7 7 THE WITNESS: He's stretched laser-cut mesh after it's been treated in 8 8 the samples of both the laser-cut and the same way. 9 the mechanically cut mesh to 50 percent 9 And one can see on the edges of the 10 elongation then let them relax. And the 10 mechanically cut mesh how the weave that has 11 mechanically cut mesh shows, as I was been -- the structure has been lost. You 11 talking about earlier, the degradation 12 12 can see the particles that have been lost in the photographic field, and you can see the of the structure of the mesh in certain 13 13 14 areas because of particle loss, whereas 14 narrowing. 15 the laser-cut mesh does not show that 15 And by contrast, you can see on the same degradation of the structure of the laser-cut mesh, you don't see the particles 16 16 17 mesh, and no particles -- or nearly no in the photographic field because there 17 18 particles haven been lost, as he terms 18 weren't the particles lost, and you can see, although there may be some narrowing from 19 it. 19 20 BY MR. GOSS: 20 the stretching, certainly not as significant and that the mesh structure has remained 21 Q. In that third paragraph, he 21 22 discusses roping. Tell the jury what roping 22 intact. 23 23 Q. And then the next page of that is. slide he discusses a -- it's entitled 24 A. It's a stretching and narrowing of 24 the mesh so that it loses its structure and 25 "Description of Side-By-Side Views." 25

		Page 434		P.	age 436
1	A. Yes.		1	Q. And about reducing risk.	
2	Q. And what does he conclude?		2	A. Yes.	
3	MS. SUTHERLAND: Objection.		3	Q. Based upon those standards and	
4	THE WITNESS: What I was just		4	based upon the documents that you've seen in	
5	describing that no particles can be seen		5	Ethicon's files, what would a reasonable,	
6	lost in the laser-cut mesh and that the		6	prudent manufacturer have done?	
7	structure of the laser-cut mesh remains		7	MS. SUTHERLAND: Objection.	
			8		
8	intact so that the integrity of the mesh			THE WITNESS: They would have	
9	across the full width of the sample		9	done the appropriate testing to first	
10	still holds in contrast to the		10	of all, they would, as I have mentioned,	
11	mechanically cut mesh where the		11	on the mechanically cut mesh, they	
12	integrity of that mesh, the structure		12	should have implemented corrective and	
13	has been lost, and there's a degradation		13	preventive action. Looking at laser-cut	
14	of the outer wale of the knit.		14	mesh could be one of those techniques,	
15	BY MR. GOSS:		15	methods that they use to do that.	
16	<ul><li>Q. Let's go to the next exhibit, the</li></ul>		16	But then, although they showed	
17	second part of the slide.		17	here that the laser-cut mesh resisted	
18	And what's that exhibit number?		18	the same degradation, then they would	
19	A. 32.		19	also need to evaluate the potential	
20	Q. Let's go to Exhibit 32. And just		20	impact on safety and effectiveness of	
21	go to the end. First of all, on Exhibit 32,		21	the laser-cut mesh as well before they	
22	does he continue to conduct elongation		22	would implement it.	
23	testing and some things you've described?		23	BY MR. GOSS:	
24	A. Yes.		24	Q. Okay. So here we are again August	
25	Q. And then what is his summary there		25	of 2006. Have you seen any documents in the	
23	Q. And then what is his summary there		23	or 2000. Thave you seem any accuments in the	
		Page 435		P	Page 437
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1 2	at the back page of Exhibit 32?  MS. SUTHERLAND: Objection.	Page 435	1 2	company's files where they have even	age 437
2	MS. SUTHERLAND: Objection.	Page 435	2	company's files where they have even suggested that they should even implement	age 437
2	MS. SUTHERLAND: Objection. BY MR. GOSS:	Page 435	2 3	company's files where they have even suggested that they should even implement any clinical testing?	age 437
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		Page 438			Page 440
1	Brown, who the document describes is a	i age 100	1	of the issues with the mechanically cut mesh	. ugc 170
2					
	product director, incontinence and pelvic		2	losing particles and stretching to the point	
3	floor repair, Gynecare worldwide division of		3	of even being a string so that it ropes, and	
4	Ethicon.		4	the laser-cut material doesn't have those	
5	Are you familiar with who Alison		5	same issues.	
6	London Brown is?		6	Q. Do you remember when we talked	
7	A. Yes, I am.		7	about the Global Harmonization Task Force	
8	Q. And it's appears to be a to a		8	standards?	
9	number of marketing people. Isn't Kevin		9	A. Yes.	
10	Mahar in marketing?		10	Q. Where we talked about minimizing	
11	A. To the best of my recollection,		11	risk, if possible?	
12	•		12	A. Yes.	
13	yes.		13		
	Q. All right. And so what I really			MS. SUTHERLAND: Objection.	
14	want to ask you about is the second		14	BY MR. GOSS:	
15	paragraph there. I want you to explain to		15	Q. Applying that standard applying	
16	the jury that second paragraph and if it's		16	that standard to this information, what	
17	important.		17	would a reasonable and prudent manufacture	r
18	MS. SUTHERLAND: Objection.		18	do?	
19	BY MR. GOSS:		19	MS. SUTHERLAND: Objection.	
20	Q. "The basic story here is that the		20	THE WITNESS: They would do the	
21	current mesh, MCM" is that mechanically		21	appropriate testing. They would do the	
22	cut mesh?		22	appropriate testing to of the	
23	A. Yes.		23	laser-cut mesh to substantiate that the	
24	Q. "Is perceived by some physicians as		24	laser-cut mesh, by the way it's cut,	
25	inferior, and we do get a high number of		25	even though it doesn't lose the	
23	interior, and we do get a high number of		23	even though it doesn't lose the	
		Page 430			Page 441
1	complaints on linting and roning" roning	Page 439	1	ctructural integrity as the mechanically	Page 441
1	complaints on linting and roping" roping	Page 439	1	structural integrity as the mechanically	Page 441
2	is what we just talked about; right?	Page 439	2	cut mesh does, they would move towards	Page 441
2	is what we just talked about; right?  A. Yes.	Page 439	2 3	cut mesh does, they would move towards implementing that but also they need to	Page 441
2 3 4	is what we just talked about; right? A. Yes. Q. And they're getting a high number	Page 439	2 3 4	cut mesh does, they would move towards implementing that but also they need to do the benefit-risk assessment for the	Page 441
2 3 4 5	is what we just talked about; right? A. Yes. Q. And they're getting a high number of complaints?	Page 439	2 3 4 5	cut mesh does, they would move towards implementing that but also they need to do the benefit-risk assessment for the laser-cut mesh and the appropriate	Page 441
2 3 4 5 6	is what we just talked about; right? A. Yes. Q. And they're getting a high number of complaints? A. That's correct.	Page 439	2 3 4 5 6	cut mesh does, they would move towards implementing that but also they need to do the benefit-risk assessment for the laser-cut mesh and the appropriate testing to ensure that the changes in	Page 441
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2 3 4 5 6 7	is what we just talked about; right? A. Yes. Q. And they're getting a high number of complaints? A. That's correct. Q. "Mesh particles falling off and the	Page 439	2 3 4 5 6 7	cut mesh does, they would move towards implementing that but also they need to do the benefit-risk assessment for the laser-cut mesh and the appropriate testing to ensure that the changes in its characteristics as a result of	Page 441
2 3 4 5 6 7 8	is what we just talked about; right?  A. Yes. Q. And they're getting a high number of complaints? A. That's correct. Q. "Mesh particles falling off and the material stretching to the point of being a	Page 439	2 3 4 5 6 7 8	cut mesh does, they would move towards implementing that but also they need to do the benefit-risk assessment for the laser-cut mesh and the appropriate testing to ensure that the changes in its characteristics as a result of cutting with the laser don't affect	Page 441
2 3 4 5 6 7 8	is what we just talked about; right? A. Yes. Q. And they're getting a high number of complaints? A. That's correct. Q. "Mesh particles falling off and the material stretching to the point of being a string. The new material would dramatically	Page 439	2 3 4 5 6 7 8 9	cut mesh does, they would move towards implementing that but also they need to do the benefit-risk assessment for the laser-cut mesh and the appropriate testing to ensure that the changes in its characteristics as a result of cutting with the laser don't affect safety and performance.	Page 441
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	is what we just talked about; right? A. Yes. Q. And they're getting a high number of complaints? A. That's correct. Q. "Mesh particles falling off and the material stretching to the point of being a string. The new material would dramatically reduce the incident of linting and should all but eliminate the roping as it stays nice it flat." And they're talking about laser-cut mesh; is that right? A. Yes. Q. Okay. So tell us the importance of that MS. SUTHERLAND: Objection. BY MR. GOSS: Q if any. A. Just that part? Q. Yeah, what we just read. A. Basically, she's saying that	Page 439	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	cut mesh does, they would move towards implementing that but also they need to do the benefit-risk assessment for the laser-cut mesh and the appropriate testing to ensure that the changes in its characteristics as a result of cutting with the laser don't affect safety and performance.  ///  BY MR. GOSS:  Q. And let's get our timing back in our heads here. Jennifer Ramirez had her surgery in September of 2010  A. That's correct.  Q right?  And she got mechanically cut mesh; is that right?  A. Yes, she did.  Q. And at the time of that surgery, was laser-cut mesh available for her?  A. Yes, it was available. It became available in fourth quarter of 2006.	Page 441

	Page 442			Page 444
1	A. Yes, it was.	1	Ethicon's files that you reviewed?	
2	Q. And had Ethicon received a number	2	A. Yes, it is.	
3	of similar complaints to the ones that you	3	Q. Is it a document that formed the	
4	just discussed, these last couple that we	4	basis of your opinions in this case?	
5	just discussed?	5	A. Yes, it is.	
6	MS. SUTHERLAND: Objection.	6	Q. Who is Martin Weisberg?	
7	THE WITNESS: Absolutely, yes.	7	A. He's the senior medical director	
8	BY MR. GOSS:	8	at this time, he was senior medical director	
9	Q. And when Jennifer got her	9	at Ethicon.	
10	mechanically cut mesh in September of 2010,	10	Q. And this document is dated	
11	even by that time, had the company done any	11	April 18, 2006?	
12	clinical testing to determine whether there	12	A. That's correct.	
13	was a difference in mechanically cut mesh	13	Q. What's a clinical expert report?	
14	versus laser-cut mesh?	14	A. It's essentially we talked	
15	MS. SUTHERLAND: Objection.	15	earlier we referred to the GHTF document	
16	THE WITNESS: No. No testing	16	on clinical evaluation, and it's basically a	
17	for that, and no testing to determine if	17	clinical evaluation that's been undertaken	
18	the linting and the fraying and the	18	by Dr. Martin Weisberg, who we just talked	
19	roping affected safety and performance,	19	about, and also a Dr. David Robinson, who is	
20	although they maintained the	20	a medical director at Ethicon, to assess	
21	mechanically cut mesh on the market.	21	clinically the laser-cut mesh.	
22	BY MR. GOSS:	22	Q. So this document, is this sometimes	
23	Q. And some of the complaints are	23	referred to as a CER?	
24	complaints that the material was stretching	24	A. Yes.	
25	to the point of being a string?	25	Q. Certified expert report?	
	Page 443			Page 445
1	MS. SUTHERLAND: Objection.	1	A. Yes.	rage 115
2	THE WITNESS: Yes.	2	Q. So the CER was intended to assess	
3	BY MR. GOSS:	3	laser-cut mesh?	
4	Q. Have you ever heard of the term	4	MS. SUTHERLAND: Objection.	
	= .			
15	DOW SUITIQUIQ ?	5	THE WITNESS: YES.	
5 6	"bow stringing"? A. Yes.	5 6	THE WITNESS: Yes. BY MR. GOSS:	
6 7	A. Yes.		BY MR. GOSS:	
6		6	BY MR. GOSS: Q. Okay. Well, did they endeavor to	
6 7	A. Yes. MS. SUTHERLAND: Objection.	6 7	BY MR. GOSS:	
6 7 8	A. Yes. MS. SUTHERLAND: Objection. BY MR. GOSS:	6 7 8	BY MR. GOSS: Q. Okay. Well, did they endeavor to assess laser-cut mesh?	
6 7 8 9	A. Yes. MS. SUTHERLAND: Objection. BY MR. GOSS: Q. Have you ever heard that in	6 7 8 9	BY MR. GOSS: Q. Okay. Well, did they endeavor to assess laser-cut mesh? A. The only testing that was done to	
6 7 8 9 10	A. Yes. MS. SUTHERLAND: Objection. BY MR. GOSS: Q. Have you ever heard that in connection with the problems that Jennifer Ramirez has? A. Yes, I have.	6 7 8 9 10	BY MR. GOSS: Q. Okay. Well, did they endeavor to assess laser-cut mesh? A. The only testing that was done to assess the laser-cut mesh was benchtop	
6 7 8 9 10 11 12 13	A. Yes. MS. SUTHERLAND: Objection. BY MR. GOSS: Q. Have you ever heard that in connection with the problems that Jennifer Ramirez has? A. Yes, I have. Q. And was Ethicon receiving	6 7 8 9 10 11	BY MR. GOSS: Q. Okay. Well, did they endeavor to assess laser-cut mesh? A. The only testing that was done to assess the laser-cut mesh was benchtop testing, and it was not done with laser-cut mesh. It was done with ultrasonicallylet's see. Some of the testing was done	
6 7 8 9 10 11 12 13	A. Yes. MS. SUTHERLAND: Objection. BY MR. GOSS: Q. Have you ever heard that in connection with the problems that Jennifer Ramirez has? A. Yes, I have. Q. And was Ethicon receiving complaints about that type of problem back	6 7 8 9 10 11 12 13 14	BY MR. GOSS: Q. Okay. Well, did they endeavor to assess laser-cut mesh? A. The only testing that was done to assess the laser-cut mesh was benchtop testing, and it was not done with laser-cut mesh. It was done with ultrasonically let's see. Some of the testing was done with ultrasonically-cut mesh, but there was	
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6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes.  MS. SUTHERLAND: Objection.  BY MR. GOSS:  Q. Have you ever heard that in connection with the problems that Jennifer Ramirez has?  A. Yes, I have.  Q. And was Ethicon receiving complaints about that type of problem back as early as May of 2005?  A. Yes.  Q. Okay. I'm going to hand you what's been marked as Exhibit 35.  A. Thank you.  (Exhibit Number 35 was marked for identification.)  BY MR. GOSS:	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	BY MR. GOSS: Q. Okay. Well, did they endeavor to assess laser-cut mesh? A. The only testing that was done to assess the laser-cut mesh was benchtop testing, and it was not done with laser-cut mesh. It was done with ultrasonically let's see. Some of the testing was done with ultrasonically-cut mesh, but there was no testing in animals, no testing in humans. Q. What do you mean by "benchtop testing"? A. Like the pictures we for example, like the pictures we were just looking at where there was it was a tensile strength test to look at the elongation of the mesh. That would be a	

	Page 446			Page 448
1	benchtop laboratory setting.	1	yes.	rage 110
2	Q. It has nothing to do with animal	2	Q. Why would a company, if you know,	
	testing?	3		
3			why would they test ultrasound mesh instead	
4	A. No.	4	of laser-cut mesh if they're trying to	
5	Q. Has nothing to do with human	5	determine that the scope as they say on	
6	testing?	6	the front page, "The project scope applies	
7	A. Not this type of testing, no.	7	to Prolene mesh laser cutting," and yet they	
8	Q. At this time let's talk about	8	don't test laser cutting.	
9	the background section there. Does it	9	MS. SUTHERLAND: Objection.	
10	describe for us the reason they're doing	10	///	
11	this testing?	11	BY MR. GOSS:	
12	A. Yes.	12	Q. Do you know any plausible reason	
13	Q. Explain to the jury why they're	13	why they did that that you've uncovered in	
14	doing why they purport to be doing the	14	their files?	
15	testing.	15	A. No. There was this was	
16	MS. SUTHERLAND: Objection.	16	inappropriate.	
17	THE WITNESS: Their rationale	17	Q. Did you find anything in their	
18	for doing this is to switch from	18	files that said, "Hey, we're out of	
19	mechanically cut as a response to, as	19	laser-cut mesh. Let's use some ultrasonic	
20	they term it, customer needs, that	20	mesh"?	
21	customers expressed a desire for a mesh	21	A. No.	
22	with smoother edges rather than edges	22	Q. Based upon your 40-plus years of	
23	with the ends of individual fibers	23	experience and your 40-plus years of	
24	exposed, which is a reference to the	24	experience where you've designed testing,	
25	fraying, and also they note that	25	clinical testing, benchmark testing, and	
23	maying, and also they note that	25	clinical testing, benefithank testing, and	
	Page 447			Page 440
1	Page 447	1	adviced companies on the appropriate tecting	Page 449
1	customer feedback has indicated there	1	advised companies on the appropriate testing	,
2	customer feedback has indicated there was some dissatisfaction with potential	2	to do for a product, would that in any way	,
2	customer feedback has indicated there was some dissatisfaction with potential fraying of the mechanically cut mesh.	2	to do for a product, would that in any way be appropriate testing for this product?	,
2 3 4	customer feedback has indicated there was some dissatisfaction with potential fraying of the mechanically cut mesh. BY MR. GOSS:	2 3 4	to do for a product, would that in any way be appropriate testing for this product? MS. SUTHERLAND: Objection.	,
2 3 4 5	customer feedback has indicated there was some dissatisfaction with potential fraying of the mechanically cut mesh. BY MR. GOSS: Q. Okay. And going to page 4, what	2 3 4 5	to do for a product, would that in any way be appropriate testing for this product? MS. SUTHERLAND: Objection. THE WITNESS: Absolutely not.	,
2 3 4 5 6	customer feedback has indicated there was some dissatisfaction with potential fraying of the mechanically cut mesh. BY MR. GOSS: Q. Okay. And going to page 4, what was the results of their testing with	2 3 4 5 6	to do for a product, would that in any way be appropriate testing for this product?  MS. SUTHERLAND: Objection.  THE WITNESS: Absolutely not.  BY MR. GOSS:	,
2 3 4 5 6 7	customer feedback has indicated there was some dissatisfaction with potential fraying of the mechanically cut mesh. BY MR. GOSS: Q. Okay. And going to page 4, what was the results of their testing with respect to particle loss?	2 3 4 5 6 7	to do for a product, would that in any way be appropriate testing for this product?  MS. SUTHERLAND: Objection.  THE WITNESS: Absolutely not.  BY MR. GOSS:  Q. And to rely on testing like that,	,
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2 3 4 5 6 7 8	customer feedback has indicated there was some dissatisfaction with potential fraying of the mechanically cut mesh. BY MR. GOSS: Q. Okay. And going to page 4, what was the results of their testing with respect to particle loss? A. That, on average, the mechanically cut mesh lost approximately twice the number	2 3 4 5 6 7 8	to do for a product, would that in any way be appropriate testing for this product?	,
2 3 4 5 6 7 8 9	customer feedback has indicated there was some dissatisfaction with potential fraying of the mechanically cut mesh. BY MR. GOSS: Q. Okay. And going to page 4, what was the results of their testing with respect to particle loss? A. That, on average, the mechanically cut mesh lost approximately twice the number of particles as the laser-cut mesh.	2 3 4 5 6 7 8 9	to do for a product, would that in any way be appropriate testing for this product?  MS. SUTHERLAND: Objection.  THE WITNESS: Absolutely not.  BY MR. GOSS:  Q. And to rely on testing like that, would it be a violation of the standard of care?  MS. SUTHERLAND: Objection.	,
2 3 4 5 6 7 8 9 10	customer feedback has indicated there was some dissatisfaction with potential fraying of the mechanically cut mesh. BY MR. GOSS: Q. Okay. And going to page 4, what was the results of their testing with respect to particle loss? A. That, on average, the mechanically cut mesh lost approximately twice the number of particles as the laser-cut mesh. Q. Did they ever, at this time or any	2 3 4 5 6 7 8 9 10	to do for a product, would that in any way be appropriate testing for this product?	,
2 3 4 5 6 7 8 9 10 11 12	customer feedback has indicated there was some dissatisfaction with potential fraying of the mechanically cut mesh. BY MR. GOSS: Q. Okay. And going to page 4, what was the results of their testing with respect to particle loss? A. That, on average, the mechanically cut mesh lost approximately twice the number of particles as the laser-cut mesh. Q. Did they ever, at this time or any time after, do any clinical testing to	2 3 4 5 6 7 8 9 10 11	to do for a product, would that in any way be appropriate testing for this product?	,
2 3 4 5 6 7 8 9 10 11 12 13	customer feedback has indicated there was some dissatisfaction with potential fraying of the mechanically cut mesh. BY MR. GOSS: Q. Okay. And going to page 4, what was the results of their testing with respect to particle loss? A. That, on average, the mechanically cut mesh lost approximately twice the number of particles as the laser-cut mesh. Q. Did they ever, at this time or any time after, do any clinical testing to determine whether losing particle loss	2 3 4 5 6 7 8 9 10 11 12 13	to do for a product, would that in any way be appropriate testing for this product?  MS. SUTHERLAND: Objection.  THE WITNESS: Absolutely not.  BY MR. GOSS: Q. And to rely on testing like that, would it be a violation of the standard of care?  MS. SUTHERLAND: Objection.  THE WITNESS: Yes, it would.  BY MR. GOSS: Q. Okay. I'm handing you what's been	,
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	customer feedback has indicated there was some dissatisfaction with potential fraying of the mechanically cut mesh. BY MR. GOSS: Q. Okay. And going to page 4, what was the results of their testing with respect to particle loss? A. That, on average, the mechanically cut mesh lost approximately twice the number of particles as the laser-cut mesh. Q. Did they ever, at this time or any time after, do any clinical testing to determine whether losing particle loss more particle loss was significant? A. No. Q. Would a reasonable and prudent manufacturer have done that? MS. SUTHERLAND: Objection. THE WITNESS: Absolutely. BY MR. GOSS:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	to do for a product, would that in any way be appropriate testing for this product?	,
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	customer feedback has indicated there was some dissatisfaction with potential fraying of the mechanically cut mesh. BY MR. GOSS: Q. Okay. And going to page 4, what was the results of their testing with respect to particle loss? A. That, on average, the mechanically cut mesh lost approximately twice the number of particles as the laser-cut mesh. Q. Did they ever, at this time or any time after, do any clinical testing to determine whether losing particle loss more particle loss was significant? A. No. Q. Would a reasonable and prudent manufacturer have done that? MS. SUTHERLAND: Objection. THE WITNESS: Absolutely. BY MR. GOSS: Q. They note that this study was	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	to do for a product, would that in any way be appropriate testing for this product?	,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	customer feedback has indicated there was some dissatisfaction with potential fraying of the mechanically cut mesh. BY MR. GOSS: Q. Okay. And going to page 4, what was the results of their testing with respect to particle loss? A. That, on average, the mechanically cut mesh lost approximately twice the number of particles as the laser-cut mesh. Q. Did they ever, at this time or any time after, do any clinical testing to determine whether losing particle lossmore particle loss was significant? A. No. Q. Would a reasonable and prudent manufacturer have done that? MS. SUTHERLAND: Objection. THE WITNESS: Absolutely. BY MR. GOSS: Q. They note that this study was performed this is on page 4 that this study was performed on ultrasonic-cut mesh	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	to do for a product, would that in any way be appropriate testing for this product?	,

		Page 450			Page 452
1	Q. And is it an Ethicon document?		1	percent of the mesh lost and the	
2	A. Yes.		2	structural integrity of that mesh	
3	Q. And it's another one of these		3	affected by the particle loss, how that	
4	string emails, is it not?		4	impacts both safety and effectiveness	
5	A. Yes.		5	when implanted.	
6	Q. Actually, I guess, it's just		6	BY MR. GOSS:	
7	A. It's a couple.		7	Q. I'm going to hand you what's been	
8	Q. Just a couple. And it involves		8	marked as Exhibit 37.	
9	Gene Kammerer. We've talked about him?		9	A. Thank you.	
10	A. Yes.		10	///	
11	Q. He's an engineering fellow?		11	(Exhibit Number 37 was	
12	A. Correct.		12	marked for identification.)	
13	Q. He's the one that did the slides we		13	BY MR. GOSS:	
14	were talking about?		14	Q. Is that a document that came from	
15	A. That's correct.		15	Ethicon's files that you reviewed?	
16	Q. And then it also has Sunny Rha,		16	A. Yes, it is.	
17	who's this identifies as operations		17	Q. Is it a document that you relied	
18	integrations, Ethicon, a Johnson & Johnson		18	upon in forming your opinions in this case?	
19	Company; is that right?		19	A. Yes, it is.	
20	A. Yes.		20	Q. And it's dated November 18 of 2003?	
21	Q. I don't want to spend a lot of time		21	A. Yes.	
22	on this, but I simply want to ask: What are		22	Q. Again, this is a document cc'ing	
23	they talking about here at the beginning of		23	Gene Kammerer. We talked about him?	
24	this about the French standards of particle		24	A. Right.	
25	loss? Explain to the jury what this		25	Q. We talked about Brian Luscombe.	ı
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	Para de la constanta de la con	Page 451		A . V	Page 453
1	discussion entailed.	Page 451	1	A. Yes.	Page 453
2	MS. SUTHERLAND: Objection.	Page 451	2	Q. It's from Marty Weisberg, and he is	Page 453
2	MS. SUTHERLAND: Objection. THE WITNESS: That there's a	Page 451	2	Q. It's from Marty Weisberg, and he is the senior medical director of Gynecare?	Page 453
2 3 4	MS. SUTHERLAND: Objection. THE WITNESS: That there's a new French standard test method for	Page 451	2 3 4	Q. It's from Marty Weisberg, and he is the senior medical director of Gynecare? A. That's correct.	Page 453
2 3 4 5	MS. SUTHERLAND: Objection. THE WITNESS: That there's a new French standard test method for determining particle loss, and the	Page 451	2 3 4 5	Q. It's from Marty Weisberg, and he is the senior medical director of Gynecare? A. That's correct. Q. I just want you to focus on the	Page 453
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3 A. Yes, it is. 3 still not conducted any clinical tests?	
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4 O. It appears to be a product pointer. 4 A. They still have not.	
1 . T	
5 Is it something that seems to be a marketing 5 Q. In fact, I think on the they	
6 document? 6 say, "As a result of the laser-cutting	
7 A. Yes. 7 process, the edges of the mesh will appear	
8 Q. Dated June 26, 2006? 8 and may feel slightly different upon	
9 A. That's correct. 9 stretching. We have conducted several bench	
10 Q. And I don't want to spend a long 10 tests."	
11 time on this, but let's just is this 11 Are those the tests we've been	
12 something that's directed to the sales 12 talking about?	
13 force?	
14 A. Yes. 14 Q. Again, what's the difference	
15 Q. And what's going on here? 15 between bench test and clinical test?	
16 A. The company is going to market the 16 A. Well, bench testing is done in a	
17 laser-cut mesh, but they are also going to 17 laboratory setting on a benchtop. It's	
18 continue to have the mechanically cut mesh 18 things like stretching the mesh and the	
19 on the market as well. 19 elongation tests that we talked about.	
20 And so they're advising they're 20 Tests of the physical properties, the	
21 advising with regard to that and providing 21 mechanical properties of the mesh.	
22 the rationale for why they're going to 22 Q. Never been tested they weren't	
23 maintain both the mechanically cut and the 23 testing it in a woman's pelvis, were they?	
24 laser-cut meshes on the market. 24 A. No, they were not.	
25 Q. What did they say about particle 25 Q. And the products on the market at	
25 Q. Tillac and they say about particle 125 Q. Tilla the products on the market at	

	Pa	age 458		Page 460
1	that time, 2006, never been tested in a	3	1	Do you want me to help you?
2	woman's pelvis; is that right?		2	A. I was just looking for the start of
3	MS. SUTHERLAND: Objection.		3	his testimony. Do you know what page number
4	THE WITNESS: That's correct.		4	it starts? Based on my prior review, it
5	BY MR. GOSS:		5	looks to be the same, but I will verify.
6	Q. Laser-cut mesh, at this point,		6	Q. On page 65, there is the total
7	before it's been launched, has it been		7	transcript, and you will see the excerpt
8	tested in a woman's pelvis?		8	that I've handed you is an excerpt from
9	A. Can you repeat your prior question?		9	there.
10	That's what I understood it to be.		10	A. Yes.
11	Q. They're about to launch laser-cut		11	Q. So reading from page 65 of that
12	mesh.		12	transcript, and I'd like for you to read to
13	A. Yes.		13	yourself page 65, lines 12, through page 66,
14	Q. At that point, has it even been		14	line 12, and let me know if that's testimony
15	tested in a woman's pelvis?		15	that you reviewed in forming your opinions
16	A. No. No.		16	in this case and whether it's something you
17			17	relied upon.
	Q. Okay. And I believe when I showed			•
18	you early on some of the testimony that you		18	A. Yes, I did.
19	had reviewed, Piet Hinoul was somebody that		19	Q. Okay. And this is March this
20	you had reviewed their testimony?		20	testimony is March 27, 2014?
21	A. Yes.		21	A. Correct.
22	(Exhibit Number 39 was		22	Q. Question this is Piet Hinoul.
23	marked for identification.)		23	He's medical director; right?
24	BY MR. GOSS:		24	A. Yes.
25	Q. I'm handing you what's been marked		25	Q. Worldwide medical director?
	D.	450		D 46
1		age 459	1	Page 46
1	as Exhibit 39 entitled "Trial Proceedings."	age 459	1	A. Yes, he was.
2	as Exhibit 39 entitled "Trial Proceedings."  And this, on the front page,	age 459	2	A. Yes, he was. Q. For Ethicon.
2	as Exhibit 39 entitled "Trial Proceedings."  And this, on the front page, identified is identified as trial	age 459	2 3	<ul><li>A. Yes, he was.</li><li>Q. For Ethicon.</li><li>A. Yes.</li></ul>
2 3 4	as Exhibit 39 entitled "Trial Proceedings."  And this, on the front page, identified is identified as trial proceedings from the Linda Batiste trial in	age 459	2 3 4	<ul><li>A. Yes, he was.</li><li>Q. For Ethicon.</li><li>A. Yes.</li><li>Q. Pretty high up.</li></ul>
2 3 4 5	as Exhibit 39 entitled "Trial Proceedings." And this, on the front page, identified is identified as trial proceedings from the Linda Batiste trial in Dallas, Texas.	age 459	2 3 4 5	<ul><li>A. Yes, he was.</li><li>Q. For Ethicon.</li><li>A. Yes.</li><li>Q. Pretty high up.</li><li>A. Very much so.</li></ul>
2 3 4 5 6	as Exhibit 39 entitled "Trial Proceedings."  And this, on the front page, identified is identified as trial proceedings from the Linda Batiste trial in Dallas, Texas.  Are you familiar with that trial?	age 459	2 3 4 5 6	<ul><li>A. Yes, he was.</li><li>Q. For Ethicon.</li><li>A. Yes.</li><li>Q. Pretty high up.</li><li>A. Very much so.</li><li>Q. "And that was the story that was</li></ul>
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		Page 462			Page 464
1	that you're paying, many of which you're		1	laser-cut mesh?	
2	paying to do studies, never any of them, you		2	MS. SUTHERLAND: Objection.	
3	never asked any of them to do that study;		3	THE WITNESS: Definitely, yes.	
4	correct?		4	BY MR. GOSS:	
5	"ANSWER: You say a lot of the		5	Q. Okay. Did your review and	
6	things in your sentence here.		6	investigation of Ethicon's files, did you	
7	"QUESTION: Have you ever asked any		7	•	
				find any documents or any PowerPoints or	
8	doctor, any paid consultant that you're		8	anything or any emails that reflected why	
9	asking to do studies, to do a study		9	Ethicon kept mechanically cut mesh on the	
10	specifically looking whether or not there is		10	market instead of just selling laser-cut	
11	more injuries to women with mechanically cut		11	mesh?	
12	mesh versus laser-cut mesh? Have you ever		12	MS. SUTHERLAND: Objection.	
13	asked anybody to do that?		13	THE WITNESS: Yes, I did.	
14	"We have not."		14	BY MR. GOSS:	
15	Did you rely upon that testimony in		15	Q. And what did those documents	
16	forming your opinions?		16	reflect?	
17	A. Yes, I did.		17	A. The TVT was the first polypropylene	
18	MS. SUTHERLAND: Objection.		18	sling kit that was on the market and had	
19	BY MR. GOSS:		19	been on the market since 1998. The compan	v
20	Q. And what's your opinion about that		20	had clinical data from the inventor and	,
21	testimony?		21	associates of the inventor dating back to	
22	MS. SUTHERLAND: Well,		22	1996 to 1998 on the product.	
23			23	•	
	objection.			Compared to other meshes that were	.
24	THE WITNESS: There was never		24	on the market, they had what they considered	J
25	any testing done. That's a violation of		25	a competitive advantage because they could	
		Page 463			Page 465
1		Page 463	1	claim having clinical data on the TVT	Page 465
1 2	the standard of care. Testing should	Page 463	1	claim having clinical data on the TVT	Page 465
2	the standard of care. Testing should have been long done long before this.	Page 463	2	retropubic product dating back to the late	Page 465
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2 3 4	the standard of care. Testing should have been long done long before this. BY MR. GOSS: Q. As of March 2014, still hadn't done	Page 463	2 3 4	retropubic product dating back to the late 1990s, and they didn't want to lose the advantage of that competitive that	Page 465
2 3 4 5	the standard of care. Testing should have been long done long before this. BY MR. GOSS:  Q. As of March 2014, still hadn't done any testing?	Page 463	2 3 4 5	retropubic product dating back to the late 1990s, and they didn't want to lose the advantage of that competitive that competitive clinical data. Or that clinical	Page 465
2 3 4 5 6	the standard of care. Testing should have been long done long before this. BY MR. GOSS: Q. As of March 2014, still hadn't done any testing? A. Still hadn't done any. Should have	Page 463	2 3 4 5 6	retropubic product dating back to the late 1990s, and they didn't want to lose the advantage of that competitive that competitive clinical data. Or that clinical data that they felt was a clinical	Page 465
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Page 466 Page 468 fraying and roping. A. Yes. 1 1 2 Q. To Dan Smith, who we talked about 2 BY MR. GOSS: 3 3 is an engineer. Q. If a manufacturer believed that 4 A. Correct. 4 mechanically cut mesh -- if they believed 5 5 Q. Was he project lead? that it caused roping, and that manufacturer 6 A. Yes. 6 believed that laser-cut mesh eliminated 7 Q. And it's "Mechanical-Cut Versus 7 roping, what do the safety principles say 8 Laser-Cut Mesh Rationale." That's what we 8 they should do? 9 9 were just talking about, wasn't it, what was MS. SUTHERLAND: Objection. 10 the reasoning, what was the rationale? 10 THE WITNESS: They should 11 A. That's correct. 11 validate through clinical testing the 12 Q. Okay. And let's go about halfway 12 laser-cut mesh to assure that the down that document. Do you see where it 13 13 difference in characteristics in the says, "Additionally," and this is Allison 14 14 laser-cut mesh versus the mechanically London Brown giving the rationale. cut mesh didn't create safety and 15 15 A. Yes. 16 16 effectiveness issue and move to market. Q. "Additionally, the mechanically cut Assuming safety and 17 17 18 TVT mesh can be stretched to deformation, 18 effectiveness was demonstrated, moved creating a rope if not placed properly." towards marketing the laser cut and 19 19 20 We've seen other documents about 20 discontinuing the mechanically cut. 21 roping? 21 BY MR. GOSS: 22 A. Yes, we have. 22 Q. Okay. Then under the second point Q. Okay. "Some physicians perceived there, I believe, this relates to what you 23 23 24 could irritate/damage the urethra, as 24 were testifying about, the clinical data and competition honed in, this aspect of the preserving the clinical data. They say, "In 25 25 Page 467 Page 469 Gynecare TVT product." 1 order to continue to claim" -- Allison 1 2 It says, "In order to alleviate 2 London Brown says, "In order to continue to concerns/meet customers needs, the team 3 3 claim the use of seven-year data in all identified two corrections." clinical studies, the MCM and LCM needed to 4 4 5 One talks about the sheath. But 5 show similar properties with physical 6 the second one says, "The use of laser 6 properties being used as a proxy for the cutting for processing which minimized 7 7 clinical needs." particulate loss as the material was 8 8 What does that mean? 9 somewhat melted as it was cut, thus keeping 9 MS. SUTHERLAND: Objection. mostly cut loops intact." 10 THE WITNESS: It means that 10 Is that consistent with the other they made the determination -- they 11 11 12 documents you've seen? 12 wanted to continue to use the clinical MS. SUTHERLAND: Objection. 13 13 data that they had dating back to the THE WITNESS: Yes, it is. late 1990s on the mechanically cut mesh, 14 14 15 BY MR. GOSS: 15 which was used in the initial TVT Q. And why is that important? product, and in order to do that, they 16 16 17 MS. SUTHERLAND: Objection. made the determination that they would 17 18 THE WITNESS: That, again, is a 18 assess physical properties, and if they document -- another document that were similar enough based on Ethicon's 19 19 20 substantiates that they knew that there 20 determination of what similar meant, then they would use that instead of 21 was an issue with mechanically cut mesh. 21 22 They knew that laser cutting mesh 22 doing clinical testing. 23 minimized the particle loss and that BY MR. GOSS: 23 that would alleviate the concerns of 24 24 Q. If Ethicon admitted that laser-cut 25 some customers who were concerned about 25 mesh was superior to mechanically cut mesh

		Page 470			Page 472
1	and offered only laser-cut mesh, is this		1	MS. SUTHERLAND: Objection.	
2	saying that they would not be able to rely		2	THE WITNESS: Yes. That was	
3	upon that seven-year data that they had		3	their concern.	
4	collected?		4	BY MR. GOSS:	
	MS. SUTHERLAND: Objection.		5		
5				Q. Should a company ever strike	
6	THE WITNESS: Yes.		6	that.	
	BY MR. GOSS:		7	Should a device manufacturer ever	
8	Q. And if they were unable to rely on		8	put profits over safety?	
9	the seven-year data that they have		9	MS. SUTHERLAND: Objection.	
10	collected, what would be the effect of that?		10	THE WITNESS: Never.	
11	MS. SUTHERLAND: Objection.		11	BY MR. GOSS:	
12	THE WITNESS: Well, their		12	Q. Is that a violation of the standard	
13	concern is if they can't show similarity		13	of care?	
14	for the laser-cut mesh, similar enough		14	THE WITNESS: Definitely.	
15	that they can maintain the use of that		15	MS. SUTHERLAND: Objection.	
16	seven-year data, that they lose that		16	BY MR. GOSS:	
17	competitive advantage because other		17	Q. Is that a violation of the safety	
18	polypropylene mesh slings that were on		18	principles that we discussed today?	
19	the market by this time didn't have that		19	MS. SUTHERLAND: Objection.	
20	old data.		20	THE WITNESS: Yes, it is.	
21	So if you look at some of the		21	MR. GOSS: Let me go for about	
22	documents we discussed earlier today,		22	another ten minutes and that will be a	
23	both patient labeling, promotional		23	good stopping point. Okay? Not forever	
24	labeling, as I recall as I sit here		24	but just a break. But we've made good	
25	today, they discuss the long-term data.		25	time, and I'm going to cut a lot out of	
		Page 471			Page 473
1	They reference the data that goes back	Page 471	1	this.	Page 473
1 2	They reference the data that goes back to the late 1990s, and so the company	Page 471	1 2		Page 473
2	to the late 1990s, and so the company	Page 471	2	MS. SUTHERLAND: Obviously, I	Page 473
2	to the late 1990s, and so the company relied on that as a competitive	Page 471	2 3	MS. SUTHERLAND: Obviously, I can't leave.	Page 473
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		Page 474			Page 476
1	BY MR. GOSS:	ruge 17 1	1	MS. SUTHERLAND: Objection.	ruge 170
2	Q. Now, over and above that particle		2	BY MR. GOSS:	
3			3	Q. Specific product code?	
	loss issue that was being discussed within				
4	the company, was there an additional issue		4	A. For a specific product code, yes.	
5	relating to particle loss with respect to		5	Q. And that included Jennifer's?	
6	the specific lot of mesh that Jennifer		6	MS. SUTHERLAND: Objection.	
7	Ramirez received?		7	BY MR. GOSS:	
8	A. Yes, there was.		8	Q. Or did that include Jennifer's?	
9	Q. What was that issue?		9	A. For the product code. This was the	
10	A. The company received two complaints		10	product code for mechanically cut mesh.	
11	on that specific lot of particle loss.		11	Q. Go to page 3. And this is a	
12	(Exhibit Number 42 was		12	PowerPoint we're looking at, is it not?	
13	marked for identification.)		13	A. Yes.	
14	BY MR. GOSS:		14	Q. And it says, on the second sentence	
15	Q. Okay. Let me hand you what's been		15	there on page 3, "The presence of Prolene	
16	marked as Exhibit 42.		16	particles in the blister is common for a	
17	Is this a document that came from		17	manual code compared to laser code."	
18	Ethicon's files?		18	Why is that important?	
19			19	·	
	A. Yes, it is.			MS. SUTHERLAND: Objection.	
20	Q. Is this a document that you		20	THE WITNESS: That is stating	
21	reviewed with respect to your opinions?		21	what we've been discussing that the	
22	A. Yes, it is.		22	manually-cut mesh has particle loss and	
23	Q. Is it a document that you relied		23	structural integrity degradation where	
24	upon with respect to your opinions?		24	the laser code does not have those	
25	A. Yes, it is.		25	same the laser-cut product does not	
-					_
		Page 475			Page 477
1	Q. And this document is entitled	Page 475	1	have those same issues.	Page 477
1 2	Q. And this document is entitled "Particles in TVT-O Blisters"?	Page 475	1 2	have those same issues. BY MR. GOSS:	Page 477
	-	Page 475		BY MR. GOSS:	Page 477
2	"Particles in TVT-O Blisters"? A. Yes.	Page 475	2		Page 477
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	Page 4	8		Page 480
1	Q. I'm sorry. July 5.	1		
2	A. Well, there are different dates on	2	, , , , , , , , , , , , , , , , , , ,	
3	here. There's July 1 to July 5.	3	, 3	
4	Q. Couple months before Jennifer's	4	p	
5	implant?	5	, ,	
6	A. Yes.	6	· · · · / · · · · · · · · · / · · · · ·	
7	Q. And it says, "Dear Darlene. Good	7	, , , , , , , , , , , , , , , , , , , ,	
8	day. I've had some quality queries about	8		
9	the product TVT obturator system. Could you	9	that product and that the product should not	
10	please answer it for me. Today our customer	10		
11	found some tiny mesh pieces (about	11	•	
12	2 millimeters) in the unopened tyvek box.	12	THE WITNESS: No.	
13	So they refused to accept the product TVT-O.	13	B BY MR. GOSS:	
14	Could you please let me know why these"	14	Q. Do you see where they did any	
15	"why did these tiny mesh pieces fall within	15	voluntary recall or even thought about doing	
16	the sterile package? Is this product with	16	a voluntary recall?	
17	tiny mesh pieces safe to be used?"	17		
18	And then the response is well,	18		
19	she then writes again does she not? on	19	BY MR. GOSS:	
20	the first page following up this email	20	Q. Any discussion of voluntary recall?	
21	string?	21		
22	MS. SUTHERLAND: Objection.	22	Q. Any discussion that you saw in	
23	THE WITNESS: Yes.	23	<u> </u>	
24	BY MR. GOSS:	24	healthcare providers that there may be a	
25	Q. She's again saying, "We received	25	problem with one of these lots?	
	David A	0		D 401
1	Page 4		MC CUTHEDIANDI Objection	Page 481
1	another three cases, same as yesterday"?	1 2		
2	MS. SUTHERLAND: Objection. THE WITNESS: Yes.	3		
3	BY MR. GOSS:	4		
5	Q. Okay. Then Darlene who she was	5	, , , , ,	
6	= .	6		
7	writing to, and Darlene is, as I understand it, she's an analyst, worldwide consumer	7	•	
8	customer quality. Does that seem right to	8		
9	you? It's not on here, but I think there's	9		
10	some emails we're about to see.	10		
11	A. That would sound right then. I	11		
12	don't recall specifically.	12		
13	Q. This is a customer quality or	13		
14	product quality issue?	14	, , ,	
15	A. Yes, it is a product quality issue.	15		
16	Q. And so Darlene Kyle writes back to	16	, -	
17		17	, , , , , , , , , , , , , , , , , , , ,	
	Kathle and she save with respect to these		5	
I 1Ω	Kathie and she says with respect to these	119		
18	particle losses showing up in the unopened	18		
19	particle losses showing up in the unopened package, "No, this is not normal nor do we	19	don't see that it actually gives the	
19 20	particle losses showing up in the unopened package, "No, this is not normal nor do we recommend using the product."	19 20	don't see that it actually gives the Q. Well, on the second page, it says	
19 20 21	particle losses showing up in the unopened package, "No, this is not normal nor do we recommend using the product."  Is that important?	19 20 21	don't see that it actually gives the Q. Well, on the second page, it says code 810081 within the	
19 20 21 22	particle losses showing up in the unopened package, "No, this is not normal nor do we recommend using the product."  Is that important?  MS. SUTHERLAND: Objection.	19 20 21 22	don't see that it actually gives the Q. Well, on the second page, it says code 810081 within the A. Right. That's the code for TVT-O.	
19 20 21 22 23	particle losses showing up in the unopened package, "No, this is not normal nor do we recommend using the product."  Is that important?  MS. SUTHERLAND: Objection.  THE WITNESS: Yes, it is.	19 20 21 22 23	don't see that it actually gives the Q. Well, on the second page, it says code 810081 within the A. Right. That's the code for TVT-O. Q. Okay. Let's move on. Anyway, so	
19 20 21 22	particle losses showing up in the unopened package, "No, this is not normal nor do we recommend using the product."  Is that important?  MS. SUTHERLAND: Objection.	19 20 21 22	don't see that it actually gives the Q. Well, on the second page, it says code 810081 within the A. Right. That's the code for TVT-O. Q. Okay. Let's move on. Anyway, so they received these complaints; right?	

	Page 482			Page 484
1	MS. SUTHERLAND: Objection.	1	THE WITNESS: No. I did not	
2	BY MR. GOSS:	2	see any testing.	
3	Q. I'm going to hand you what's been	3	BY MR. GOSS:	
4	marked as Exhibit 44.	4	Q. Did you find anything like that in	
5	(Exhibit Number 44 was	5	their files?	
6	marked for identification.)	6	A. No, I did not.	
7	BY MR. GOSS:	7	Q. If there was no such analysis in	
8	Q. Do you recognize that document?	8	their files, there was not any such analysis	
9	A. Yes, I do.	9	done, to make a statement that it was	
10	Q. And is that a document that came	10	remote, would that be a violation of the	
11	from Ethicon's files?	11	standard in the industry?	
12	A. Yes, it is.	12	MS. SUTHERLAND: Objection.	
13	Q. Is it a document that you relied	13	THE WITNESS: Yes, it would.	
14	upon?	14	BY MR. GOSS:	
15	A. Yes, it is.	15	Q. Okay. I have two more, and then we	
	Q. And who's Meng Chen?			
16	•	16	can break. I'm handing you what's been marked as Exhibit 45.	
17	A. She is an associate medical	17		
18	director.	18	A. Thank you.	
19	Q. And Carolyn Brennan, who appears to	19	(Exhibit Number 45 was	
20	be a manager of women's health and urology,	20	marked for identification.)	
21	worldwide customer quality?	21	BY MR. GOSS:	
22	A. Correct.	22	Q. This is another one of those email	
23	Q. This, again, is addressing this	23	chains.	
24	particle loss issue?	24	A. Yes.	
25	A. Yes, it is.	25	Q. So we start from the back. First	
				-
	D 103			
	Page 483			Page 485
1	MS. SUTHERLAND: Objection.	1	of all, let's identify some of these people	Page 485
2	MS. SUTHERLAND: Objection. BY MR. GOSS:	2	of all, let's identify some of these people in this document. First of all, is this a	Page 485
2	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an	2 3	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?	Page 485
2 3 4	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director?	2 3 4	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is.	Page 485
2	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is.	2 3	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is.  Q. Is it a document that you reviewed	Page 485
2 3 4	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with	2 3 4 5 6	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is.  Q. Is it a document that you reviewed with respect to your opinions?	Page 485
2 3 4 5	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary	2 3 4 5 6 7	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is.  Q. Is it a document that you reviewed with respect to your opinions?  A. Yes, it is.	Page 485
2 3 4 5 6	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with	2 3 4 5 6	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions? A. Yes, it is. Q. Is it a document that you relied	Page 485
2 3 4 5 6 7	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary	2 3 4 5 6 7	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions?  A. Yes, it is. Q. Is it a document that you relied upon in forming your opinions?	Page 485
2 3 4 5 6 7 8	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary Brennan there in the middle of the page.	2 3 4 5 6 7 8	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions? A. Yes, it is. Q. Is it a document that you relied	Page 485
2 3 4 5 6 7 8	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary Brennan there in the middle of the page. She says, "After careful review of the	2 3 4 5 6 7 8	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions?  A. Yes, it is. Q. Is it a document that you relied upon in forming your opinions?	Page 485
2 3 4 5 6 7 8 9	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary Brennan there in the middle of the page. She says, "After careful review of the available information in the files and	2 3 4 5 6 7 8 9	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions? A. Yes, it is. Q. Is it a document that you relied upon in forming your opinions? A. Yes, it is.	
2 3 4 5 6 7 8 9 10	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary Brennan there in the middle of the page. She says, "After careful review of the available information in the files and information provided by the manufacturing	2 3 4 5 6 7 8 9 10	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions? A. Yes, it is. Q. Is it a document that you relied upon in forming your opinions? A. Yes, it is. Q. And looks like this is another	
2 3 4 5 6 7 8 9 10 11 12	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary Brennan there in the middle of the page. She says, "After careful review of the available information in the files and information provided by the manufacturing site, the business unit medical director and	2 3 4 5 6 7 8 9 10 11	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions? A. Yes, it is. Q. Is it a document that you relied upon in forming your opinions? A. Yes, it is. Q. And looks like this is another document involving Darlene Kyle. Remember	
2 3 4 5 6 7 8 9 10 11 12 13	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary Brennan there in the middle of the page. She says, "After careful review of the available information in the files and information provided by the manufacturing site, the business unit medical director and I feel that the possibility for the tiny	2 3 4 5 6 7 8 9 10 11 12 13	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions?  A. Yes, it is. Q. Is it a document that you relied upon in forming your opinions?  A. Yes, it is. Q. And looks like this is another document involving Darlene Kyle. Remember said earlier, she was an analyst, worldwide	
2 3 4 5 6 7 8 9 10 11 12 13 14	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary Brennan there in the middle of the page. She says, "After careful review of the available information in the files and information provided by the manufacturing site, the business unit medical director and I feel that the possibility for the tiny tape fragments observed in these five cases	2 3 4 5 6 7 8 9 10 11 12 13 14	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions?  A. Yes, it is. Q. Is it a document that you relied upon in forming your opinions?  A. Yes, it is. Q. And looks like this is another document involving Darlene Kyle. Remember said earlier, she was an analyst, worldwide customer quality.	
2 3 4 5 6 7 8 9 10 11 12 13 14 15	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary Brennan there in the middle of the page. She says, "After careful review of the available information in the files and information provided by the manufacturing site, the business unit medical director and I feel that the possibility for the tiny tape fragments observed in these five cases to cause adverse consequences in a patient,	2 3 4 5 6 7 8 9 10 11 12 13 14 15	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions? A. Yes, it is. Q. Is it a document that you relied upon in forming your opinions? A. Yes, it is. Q. And looks like this is another document involving Darlene Kyle. Remember said earlier, she was an analyst, worldwide customer quality.  Do you see that on the last page?	
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary Brennan there in the middle of the page. She says, "After careful review of the available information in the files and information provided by the manufacturing site, the business unit medical director and I feel that the possibility for the tiny tape fragments observed in these five cases to cause adverse consequences in a patient, a device administrator or others should be	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions? A. Yes, it is. Q. Is it a document that you relied upon in forming your opinions? A. Yes, it is. Q. And looks like this is another document involving Darlene Kyle. Remember said earlier, she was an analyst, worldwide customer quality.  Do you see that on the last page? A. Yes, I do. Thank you.	
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary Brennan there in the middle of the page. She says, "After careful review of the available information in the files and information provided by the manufacturing site, the business unit medical director and I feel that the possibility for the tiny tape fragments observed in these five cases to cause adverse consequences in a patient, a device administrator or others should be considered remote. The presence of tiny tape fragments in the product package is not	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions? A. Yes, it is. Q. Is it a document that you relied upon in forming your opinions? A. Yes, it is. Q. And looks like this is another document involving Darlene Kyle. Remember said earlier, she was an analyst, worldwide customer quality.  Do you see that on the last page? A. Yes, I do. Thank you. Q. And also I see Meng Chen's also	
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary Brennan there in the middle of the page. She says, "After careful review of the available information in the files and information provided by the manufacturing site, the business unit medical director and I feel that the possibility for the tiny tape fragments observed in these five cases to cause adverse consequences in a patient, a device administrator or others should be considered remote. The presence of tiny tape fragments in the product package is not expected to change the product safety	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions?  A. Yes, it is. Q. Is it a document that you relied upon in forming your opinions?  A. Yes, it is. Q. And looks like this is another document involving Darlene Kyle. Remember said earlier, she was an analyst, worldwide customer quality.  Do you see that on the last page?  A. Yes, I do. Thank you. Q. And also I see Meng Chen's also copied on these emails. We just talked about her.	
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary Brennan there in the middle of the page. She says, "After careful review of the available information in the files and information provided by the manufacturing site, the business unit medical director and I feel that the possibility for the tiny tape fragments observed in these five cases to cause adverse consequences in a patient, a device administrator or others should be considered remote. The presence of tiny tape fragments in the product package is not expected to change the product safety profile."	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions?  A. Yes, it is. Q. Is it a document that you relied upon in forming your opinions?  A. Yes, it is. Q. And looks like this is another document involving Darlene Kyle. Remember said earlier, she was an analyst, worldwide customer quality.  Do you see that on the last page?  A. Yes, I do. Thank you. Q. And also I see Meng Chen's also copied on these emails. We just talked about her.  A. Correct.	
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary Brennan there in the middle of the page. She says, "After careful review of the available information in the files and information provided by the manufacturing site, the business unit medical director and I feel that the possibility for the tiny tape fragments observed in these five cases to cause adverse consequences in a patient, a device administrator or others should be considered remote. The presence of tiny tape fragments in the product package is not expected to change the product safety profile."  Does it first of all, did you	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions?  A. Yes, it is. Q. Is it a document that you relied upon in forming your opinions?  A. Yes, it is. Q. And looks like this is another document involving Darlene Kyle. Remember said earlier, she was an analyst, worldwide customer quality.  Do you see that on the last page?  A. Yes, I do. Thank you. Q. And also I see Meng Chen's also copied on these emails. We just talked about her.  A. Correct. Q. And Shalot Armstrong. She's a	
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary Brennan there in the middle of the page. She says, "After careful review of the available information in the files and information provided by the manufacturing site, the business unit medical director and I feel that the possibility for the tiny tape fragments observed in these five cases to cause adverse consequences in a patient, a device administrator or others should be considered remote. The presence of tiny tape fragments in the product package is not expected to change the product safety profile."  Does it first of all, did you see anywhere where they did any testing, or	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions?  A. Yes, it is. Q. Is it a document that you relied upon in forming your opinions?  A. Yes, it is. Q. And looks like this is another document involving Darlene Kyle. Remember said earlier, she was an analyst, worldwide customer quality.  Do you see that on the last page?  A. Yes, I do. Thank you. Q. And also I see Meng Chen's also copied on these emails. We just talked about her.  A. Correct. Q. And Shalot Armstrong. She's a manager it appears manager I think	
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary Brennan there in the middle of the page. She says, "After careful review of the available information in the files and information provided by the manufacturing site, the business unit medical director and I feel that the possibility for the tiny tape fragments observed in these five cases to cause adverse consequences in a patient, a device administrator or others should be considered remote. The presence of tiny tape fragments in the product package is not expected to change the product safety profile."  Does it first of all, did you see anywhere where they did any testing, or there was any analysis done at all to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions?  A. Yes, it is. Q. Is it a document that you relied upon in forming your opinions?  A. Yes, it is. Q. And looks like this is another document involving Darlene Kyle. Remember said earlier, she was an analyst, worldwide customer quality.  Do you see that on the last page?  A. Yes, I do. Thank you. Q. And also I see Meng Chen's also copied on these emails. We just talked about her.  A. Correct. Q. And Shalot Armstrong. She's a manager it appears manager I think she's a manager in quality systems and	
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And Meng Chen, isn't she an associate medical director? A. Yes, she is. Q. And Meng Chen responds with addressing this issue responds to Cary Brennan there in the middle of the page. She says, "After careful review of the available information in the files and information provided by the manufacturing site, the business unit medical director and I feel that the possibility for the tiny tape fragments observed in these five cases to cause adverse consequences in a patient, a device administrator or others should be considered remote. The presence of tiny tape fragments in the product package is not expected to change the product safety profile."  Does it first of all, did you see anywhere where they did any testing, or	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	of all, let's identify some of these people in this document. First of all, is this a document that came from Ethicon's files?  A. Yes, it is. Q. Is it a document that you reviewed with respect to your opinions?  A. Yes, it is. Q. Is it a document that you relied upon in forming your opinions?  A. Yes, it is. Q. And looks like this is another document involving Darlene Kyle. Remember said earlier, she was an analyst, worldwide customer quality.  Do you see that on the last page?  A. Yes, I do. Thank you. Q. And also I see Meng Chen's also copied on these emails. We just talked about her.  A. Correct. Q. And Shalot Armstrong. She's a manager it appears manager I think	

		Page 486			Page 488
1	A. That sounds right, to the best of		1	THE WITNESS: No, I have not.	
2	my recollection.		2	BY MR. GOSS:	
3	•		3		1
	Q. Okay. And they're talking about			Q. Okay. Well, let me did the	
4	if you go to the bottom of page 1, and they		4	company have a corporate policy regarding	1
5	ask Darlene's asking Carlos Lugo-Ponce		5	careful communications?	1
6	they're discussing this issue about whether		6	MS. SUTHERLAND: Objection.	
7	or not it's safe despite small pieces of		7	THE WITNESS: Yes, it did.	1
8	mesh that are being found in the packaging.		8	(Exhibit Number 46 was	
9	Do you see that?		9	marked for identification.)	
10	A. Yes, I do.		10	///	1
11	Q. And what I want to ask you about is		11	BY MR. GOSS:	
12	Carlos Lugo-Ponce's response at the top		12	Q. I'm handing you what's been marked	
13	there is "Darlene, First, I recommend a		13	as Exhibit 46. And is this a document that	
14	meeting rather than an email chain." And		14	you reviewed in is this a document from	
15	then he talks about at the bottom still		15	Ethicon's files?	
16	needing "a detailed understanding of how		16	A. Yes, it is.	
17	this happens in the manufacturing floor,		17	Q. Is this a document that you	l
18	what defect classification this is, and how		18	reviewed in connection with forming your	
19	frequent this is."		19	opinions in this case?	
20	He's talking about is he talking		20	A. Yes, it is.	
21	about the product?		21	Q. And it's entitled "Introduction to	
22	MS. SUTHERLAND: Objection.		22	HCC: Key Takeaways and Contacts." And it's	;
23	THE WITNESS: Yes, he is.		23	talking about mission statement for HCC. By	
24	BY MR. GOSS:		24	the way, do you know what HCC is?	
25	Q. Is he talking about a		25	A. Yes. It stands for healthcare	
		Page 487			Page 489
1	product-related issue?	Page 487	1	compliance.	Page 489
1 2	product-related issue?  A. Yes.	Page 487	1 2	compliance.  O. Okay. And we just talked about the	Page 489
2	A. Yes.	Page 487	2	Q. Okay. And we just talked about the	Page 489
2 3	A. Yes. MS. SUTHERLAND: Objection.	Page 487	2 3	Q. Okay. And we just talked about the email where they were talking about the	
2 3 4	A. Yes. MS. SUTHERLAND: Objection. BY MR. GOSS:	Page 487	2 3 4	Q. Okay. And we just talked about the email where they were talking about the product and product performance, and Carlos	
2 3 4 5	A. Yes.  MS. SUTHERLAND: Objection.  BY MR. GOSS:  Q. And product performance issue?	Page 487	2 3 4 5	Q. Okay. And we just talked about the email where they were talking about the product and product performance, and Carlos Lugo said let's not do this in writing?	
2 3 4 5 6	A. Yes.  MS. SUTHERLAND: Objection.  BY MR. GOSS:  Q. And product performance issue?  A. Yes. Product quality issue.	Page 487	2 3 4 5 6	Q. Okay. And we just talked about the email where they were talking about the product and product performance, and Carlos Lugo said let's not do this in writing?  A. Yes.	
2 3 4 5 6 7	A. Yes.  MS. SUTHERLAND: Objection.  BY MR. GOSS: Q. And product performance issue? A. Yes. Product quality issue. Q. Okay. And his first sentence there	Page 487	2 3 4 5 6 7	Q. Okay. And we just talked about the email where they were talking about the product and product performance, and Carlos Lugo said let's not do this in writing?  A. Yes.  MS. SUTHERLAND: Objection.	
2 3 4 5 6 7 8	A. Yes. MS. SUTHERLAND: Objection. BY MR. GOSS: Q. And product performance issue? A. Yes. Product quality issue. Q. Okay. And his first sentence there is "First, I recommend a meeting rather than	Page 487	2 3 4 5 6 7 8	Q. Okay. And we just talked about the email where they were talking about the product and product performance, and Carlos Lugo said let's not do this in writing?  A. Yes.  MS. SUTHERLAND: Objection. BY MR. GOSS:	
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	Page 490			Page 492
1	message" let me start over.	1	remote?	
2	"With regards to electronic	2	MS. SUTHERLAND: Objection.	
3	communications, including email and text	3	THE WITNESS: No.	
4	messaging, it is important to note no	4	MR. GOSS: Okay. Let's take a	
5	product claims should ever be communicated	5	break.	
6	via email or text messaging."	6	THE VIDEOGRAPHER: With the	
7	Do you see that?	7	approval of counsel, going off the	
8	A. Yes.	8	record. The time is approximately	
9	Q. And was what they were talking	9	8:18 p.m.	
10	about in those last emails, were they	10	(Recess taken from	
11	product claims?	11	8:18 p.m. to 8:30 p.m.)	
12	MS. SUTHERLAND: Objection.	12	MR. GOSS: Let's go on the	
13	THE WITNESS: It relates to	13	record.	
14	product claims, yes.	14	It's been a long day. I've	
15	BY MR. GOSS:	15	looked at my notes. I think I probably	
16	Q. Okay. And the company's policy is	16	have time left of almost three hours. I	
17	this: "Be very cognizant of what you're	17	think that I would probably, from the	
18	communicating electronically as any and all	18	looks of my notes, get close to using	
19	forms of communications can be discoverable	19	all that. It's now is it 8:30 our	
20	in a court of law."	20	time? 8:30 California time, 10:30	
21	Did I read that right?	21	Dallas time.	
22	A. Yes.	22	The court reporter has told me	
23	MS. SUTHERLAND: Objection.	23	she doesn't have three hours left in	
24	BY MR. GOSS:	24	her. I think I believe her. And I've	
25	Q. Is that this company's careful	25	talked with the witness.	
23	Q. 13 that this company 3 careful	25	taiked with the withess.	
	Page 491			Page 493
1	Page 491 communication policy?	1	Peggy, you can be made	Page 493
1 2		1 2	Peggy, you can be made available next Thursday or Friday for	Page 493
	communication policy?			Page 493
2	communication policy? A. Yes. It's a part of it, yes.	2	available next Thursday or Friday for	Page 493
2 3	communication policy? A. Yes. It's a part of it, yes. Q. I mean, should a reasonable and	2 3	available next Thursday or Friday for two-and-a-half hours.	Page 493
2 3 4	communication policy? A. Yes. It's a part of it, yes. Q. I mean, should a reasonable and prudent manufacturer be concerned about its claims, its product claims and complaints by	2 3 4	available next Thursday or Friday for two-and-a-half hours.  THE WITNESS: That's correct.  MR. GOSS: Okay. I'm	Page 493
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2 3 4 5 6 7	communication policy?  A. Yes. It's a part of it, yes. Q. I mean, should a reasonable and prudent manufacturer be concerned about its claims, its product claims and complaints by customers, when handling those complaints, should they be concerned about what's going	2 3 4 5 6	available next Thursday or Friday for two-and-a-half hours.  THE WITNESS: That's correct.  MR. GOSS: Okay. I'm available. I understand the doctor's lawyer will make somebody available, and	Page 493
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١,	sawa sh2	Page 494	4	REPORTER'S CERTIFICATE	Page 496
1	correct?		1 2	REPORTER'S CERTIFICATE	
2	MR. GOSS: Right.		3	The undersigned Certified Shorthand	
	MS. SUTHERLAND: All right.		4	Reporter licensed in the State of California	
4	And I would just note an objection to		5	does hereby certify:	
5	that, that plaintiffs did not		6	That the foregoing deposition was	
6	cross-notice this deposition. I had no		7	taken before me at the time and place	
7	notice that this was going to be a trial		8	therein set forth, at which time the witness	
8	deposition. I certainly didn't prepare		9	was duly sworn by me;	
9	for a trial cross-exam, and so I would		10	That the testimony of the witness	
10	preserve whatever objection might		11	and all objections made at the time of the	
11	possibly be available to me under Texas		12	examination were recorded stenographically	
12	law to come back and do a thorough		13	by me and were thereafter transcribed, said	
13	cross-exam of the witness, either me or		14 15	transcript being a true copy of my shorthand notes thereof.	
14	somebody from the trial team.		16	I further declare that I have no	
15	MR. GOSS: I note your		17	interest in the outcome of the action.	
16	objection. I don't agree with it under			In witness whereof, I have	
17	Texas law. We didn't have to		18	subscribed my name this 30th day of March,	
18	cross-notice it. Anyway, we don't have		19	2016.	
19	to argue about that. I got your				
20	objection.		20		
21	MS. SUTHERLAND: Yeah. It is		21		_
22	what it is. I had my marching orders to		22	LISA MOSKOWITZ	
23	get that on the record, and I have.		23	CSR 10816, RPR, CRR, CLR	
24	MR. GOSS: You've got to tell		24 25	NCRA Realtime Systems Administrator	
25	your local anyway, we don't need to		25		
		Page 495			
		raue 493			Page 497
1	get into that. It's been a long day.	rage 495	1	LAWYER'S NOTES	Page 497
1 2	get into that. It's been a long day. Thanks, everybody. I think we all	rage 493	1 2	LAWYER'S NOTES PAGE LINE	Page 497
2	Thanks, everybody. I think we all	rage 493	2	LAWYER'S NOTES PAGE LINE	Page 497
2 3	Thanks, everybody. I think we all cooperated, and obviously, I'm not	raye 493	2		Page 497 -
2 3 4	Thanks, everybody. I think we all cooperated, and obviously, I'm not passing the witness. We're adjourned.	raye 453	2 3 4		Page 497 - -
2 3 4 5	Thanks, everybody. I think we all cooperated, and obviously, I'm not passing the witness. We're adjourned.  MS. SUTHERLAND: Right. And as	rage 493	2		Page 497
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2 3 4 5 6	Thanks, everybody. I think we all cooperated, and obviously, I'm not passing the witness. We're adjourned.  MS. SUTHERLAND: Right. And as soon as I know which day will work for coverage, I will let everybody know.	rage 493	2 3 4 5 6		Page 497
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